Supreme Court, U.S.
FILED

No. 03-____

03 779 NOV 24 2003

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

—v.—

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC., THE STOP & SHOP SUPERMARKET CO., WALGREEN CO., ECKERD CORP., CVS MERIDIAN, INC., and RITE AID CORP., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

LOUIS M. SOLOMON
Counsel of Record
CLAUDE M. MILLMAN
PROSKAUER ROSE LLP
1585 Broadway
New York, New York 10036
(212) 969-3000

DAVID A. STRAUSS
1111 East 60th Street
Chicago, Illinois 60637
(773) 702-9601

Counsel for Petitioner

Supreme Court, U.S.
FILED
NOV 26 2003
OFFICE OF THE CLERK

QUESTION PRESENTED

Whether an interim settlement of patent infringement litigation, in which the alleged infringer, for consideration, agrees to keep its product off the market until the claim of infringement is resolved, constitutes a *per se* violation of the Sherman Antitrust Act, irrespective of the validity of the claim of infringement or the reasonableness of the interim settlement.

PARTIES TO THE PROCEEDING

In addition to the parties named in the caption, the following parties appeared below but are believed to have no remaining interest in the outcome of the petition:

Adverse to Andrx Pharmaceuticals, Inc.

Charles Zuccarini,
Joseph D'Esposito,
Shirlean Glover,
Larry S. Sizemore,
Albert Eirich,
Eugenia Wynne Sams,
Aetna, Inc.,
Cobalt Corporation,
Duane Reade, Inc., and
Louisiana Wholesale Drug Company

Not Adverse to Andrx Pharmaceuticals, Inc.

Hoechst Marion Roussel, Inc. (now Aventis Pharmaceuticals Inc.)

CORPORATE DISCLOSURE STATEMENT

Petitioner Andrx Pharmaceuticals, Inc. is a wholly-owned subsidiary of Andrx Corporation. Andrx Corporation is a publicly traded company.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i
PARTIES TO THE PROCEEDING ii
CORPORATE DISCLOSURE STATEMENT ii
TABLE OF AUTHORITIES v
OPINIONS BELOW 1
STATEMENT OF JURISDICTION 1
STATUTORY PROVISIONS INVOLVED 1
STATEMENT OF THE CASE 1
REASONS FOR GRANTING THE PETITION 7
I. This Court Should Grant Certiorari To Resolve the Conflict Between the Sixth and Eleventh Circuits 9
II. If the Circuit Split Is Not Resolved, the Lower Courts Will Continue To Apply Radically Inconsistent Rules to Patent Settlements 12
A. Other Antitrust Challenges to Patent Infringement Settlements Will Soon Reach the Appellate Courts 12
B. The Issue Is Not Confined to the Pharmaceutical Industry 16
C. The Multidistrict Nature of Antitrust Challenges to Patent Infringement Settlements Exacerbates the Circuit Split 18
III. The Question Presented Is One of Great Importance 19
A. The Sixth Circuit's Decision Upsets the Critical Balance Between the Patent and Antitrust Laws 21
B. The Sixth Circuit's Decision Devalues Intellectual Property Rights 25
C. The Issue Has Been Fully Debated and Is Ripe For Resolution 27
CONCLUSION 30
APPENDIX 1a
Opinion of the Sixth Circuit 1a

Opinion of the District Court.....34a

Order of the Sixth Circuit Granting The Defendant's Petition For Leave To Appeal 83a

Order of the Sixth Circuit Denying The Defendant's Petition For Rehearing En Banc 86a

Statutory Provisions.....88a

Stipulation and Agreement.....97a

Opinion of the Eleventh Circuit 115a

TABLE OF AUTHORITIES

Cases

Asahi Glass Co. v. Pentech Pharm., Inc., ___ F. Supp. 2d ___, 2003 WL 22462405 (N.D. Ill. Oct. 29, 2003) ..... passim

B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419 (Fed. Cir. 1997) 24

Blonder-Tongue Labs., Inc. v. University of Ill. Found., 402 U.S. 313 (1971) 21

BMI v. CBS, 441 U.S. 1 (1979) 23, 24

Business Elecs. Corp. v. Sharp Elecs. Corp., 485 U.S. 717 (1988) 22

California Dental Ass'n v. FTC, 526 U.S. 756 (1999) 22, 23

In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682 (E.D. Mich. 2000) 1

In re Cardizem CD Antitrust Litig., 1999 U.S. Dist. LEXIS 9285 (J.P.M.L. 1999) 10

In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003) 1, 2, 10

In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188 (E.D.N.Y. 2003) 13

Continental T.V. v. GTE Sylvania, 433 U.S. 36 (1977) 25

E. Bement & Sons v. National Harrow Co., 186 U.S. 70 (1902) 23

Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) 3

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002) 21

Graham v. John Deere Co., 383 U.S. 1 (1966) 21

In re Independent Serv. Orgs. Antitrust Litig., 203 F.3d 1322 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001) 24

Intergraph Corp. v. Intel Corp., 195 F.3d 1346 (Fed. Cir. 1999) 24

Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26 (1998) 18

Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700 (Fed. Cir. 1992) 24

Moore v. Valder, 65 F.3d 189 (D.C. Cir. 1995) 19

Murphy v. FDIC, 208 F.3d 959 (11th Cir. 2000) 19

Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co., 472 U.S. 284 (1985) 23

In re Schering-Plough Corp., FTC Docket No. 9297, 2002 WL 1488085 (ALJ Decision June 27, 2002) 13, 15, 17

Standard Oil Co. v. United States, 283 U.S. 163 (1931) 24

Stickle v. Heublein, Inc., 716 F.2d 1550 (Fed. Cir. 1983) 4

In re Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121 (E.D.N.Y. 2003), appeal docketed *sub nom. Tamoxifen Citrate v. Barr Labs., Inc.*, No. 03-7641 (2d Cir. June 20, 2003) 13, 14

Tamoxifen Citrate v. Barr Labs., Inc., No. 03-7641 (2d Cir. June 20, 2003) 14

In re Terazosin Hydrochloride Antitrust Litig., 1999 U.S. Dist. LEXIS 19640 (J.P.M.L. 1999) 10

United States v. Generix Drug Corp., 460 U.S. 453 (1983) 3

United States v. Singer Mfg. Co., 374 U.S. 174 (1963) 8

United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122 (D.C. Cir. 1981) 12

Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003) ..... passim

Statutes

15 U.S.C. § 1 1

21 U.S.C. § 355 ..... 3, 4, 5

35 U.S.C. § 154 ..... 1, 3, 22, 25

35 U.S.C. § 261 ..... 1, 3, 22

35 U.S.C. § 271 ..... 1, 4

35 U.S.C. § 282 ..... 1, 4

35 U.S.C. § 284 ..... 1, 4

28 U.S.C. § 1254 1

28 U.S.C. § 1292 7

28 U.S.C. § 1407 18

Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Hatch-Waxman Act) 1, 3

Other Authorities

AIPLA, *Testimony Before FTC and Antitrust Division on Antitrust & Intellectual Property Issues* (April 10, 2002) (at www.ftc.gov) 25

Sheila F. Anthony, *Riddles and Lessons from the Prescription Drug Wars: Antitrust*

Implications of Certain Types of Agreements Involving Intellectual Property (2000) (at www.ftc.gov) 28

Naomi Aoki, *Drugmakers Poised for Battle Brand Name Firms Up Stakes In Face of Generic Competition*, Boston Globe, November 26, 2001, at D1 6

William F. Baxter, *Vertical Practices*, 52 Antitrust L.J. 743 (1983) 25

Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, Antitrust Bull. 491 (Summer-Fall 2002) 28

Yee Wah Chin & Thomas G. Krattenmaker, *Antitrust Update*, M&A Tax J. 30 (December 2001) 28

Thomas F. Cotter, *Refining the "Presumptive Illegality": Approach to Settlements of Patent Disputes Involving Reverse Payments*, 87 Minn. L. Rev. 1789 (2003) 29

Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747 (2003) 17, 29

Frank H. Easterbrook, *The Limits of Antitrust*, 63 Texas L. Rev. 1 (1984) 23

FDA Proposed Rules: ANDA Regulations, 54 Fed. Reg. 28,872 (July 10, 1989) 4

Federal Judicial Caseload Statistics, Table C-4 U.S. District Courts – Civil Cases Terminated, by Nature of Suit and Action Taken, During the 12-Month Period Ending March 31, 2002 (March 31, 2002) (at www.uscourts.gov) 18

FTC, *Bristol-Myers Squibb Co.: Analysis to Aid Public Comment*, 68 Fed. Reg. 12080 (March 13, 2003) 13

FTC, *Generic Drug Entry Prior to Patent Expiration* (July 2002) (at www.ftc.gov)..... passim

FTC, *Hoechst Marion Roussel, Inc., et al.: Analysis to Aid Public Comment*, 66 Fed. Reg. 18636 (April 10, 2001) 7

Matthew Herper, *Solving the Drug Patent Problem,* Forbes.com (May 2, 2002) (at www.forbes.com) 26

IND Filings Hit Seven-Year Low in 2003; Where is R&D Productivity, Prescription Pharma. & Biotechnology (Nov. 10, 2003)..... 26

IPO, *Comments on the Joint Hearings of the FTC and DOJ Regarding Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (Nov. 15, 2002) (at www.ftc.gov)..... 25

James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 Antitrust L. J. 777 (2003) 29

Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Part II* (2001) (at www.ftc.gov)..... 28

Keith Leffler & Cristopher Leffler, *The Probabilistic Nature of Patent Rights*, 17 Antitrust 77 (Summer 2003) 29

Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic"*

Patent Rights and False Positives, 17 Antitrust 68 (Spring 2003) 29

H. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 Geo. Mason L. Rev. 359 (2002) 8

Jayne O'Donnell, *FTC Targets Deal to Keep Generic Off Shelf*, USA Today, Sept. 30, 1999, at Money, 1B 20

Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 Minn. L. Rev. 1767 (2003) 29

R. Hewitt Pate, *Antitrust and Intellectual Property*, Address to the American Intellectual Property Law Association (2003) (at www.usdoj.gov) 20, 27, 28

Robert Pear, *AARP Wants Bigger Role in Prescription Drug Cases*, N.Y. Times, April 23, 2002, at A14 21

PhMRA, *Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights* (April 22, 2002) (at www.ftc.gov) 26

Robert Pitofsky, Statement of the FTC Before the House Judiciary Committee (2000) (at www.ftc.gov) 20

Richard A. Posner, *Antitrust and the New Economy*, 68 Antitrust L.J. 925 (2001) 13

Richard A. Posner, *Antitrust Law* (2d ed. 2001) 13

Gauri Prakash-Canjels, *Trends in Patent Cases: 1990-2000*, 41 IDEA 283 (2001) 18

Peter J. Prommer, *Note: The Pioneer and Generic Drug Manufacturer Agreements: Is the Sherman Act Big Enough to Swallow These Pills?*, 2002 J. L. Tech. & Pol'y 215 (Spring 2002) 29

In re Schering-Plough, Appeal Brief Of Counsel Supporting the Complaint, August 9, 2002 (2002 WL 1941700) 15

Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, 17 Antitrust 70 (Summer 2003) 29

Peter Spiegel, *U.S. To Widen Drug Groups Inquiry: FTC Investigation Could Lead to New Wave of Lawsuits*, Financial Times (London), July 6, 2001, at 17 21

Sheryl Gay Stolberg & Jeff Gerth, *Keeping Down the Competition: How Companies Stall Generics And Keep Themselves Healthy*, N.Y. Times, July 23, 2000, at Section 1, page 1 21

Valley Drug Co. v. Abbott Labs., No. 02-12091-J, Appellees' Petition for Rehearing En Banc (11th Cir. Oct. 6, 2003) 9, 16, 20

James J. Wheaton, *Generic Competition and Pharmaceutical Innovation*, 35 Cath. U. L. Rev. 433 (1986) 2, 3

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-33a) is reported at 332 F.3d 896 (6th Cir. 2003). The district court's opinion (Pet. App. 34a-82a) is reported at 105 F. Supp. 2d 682 (E.D. Mich. 2000).

STATEMENT OF JURISDICTION

The court of appeals' judgment was entered on June 13, 2003. Pet. App. 1a. A timely petition for rehearing was denied on July 24, 2003. Pet. App. 86a-87a. On October 6, 2003, Justice Stevens extended the time in which to file a petition for a writ of certiorari to December 5, 2003. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Portions of 35 U.S.C. §§ 154, 261, 271, 282, 284, Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and portions of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Hatch-Waxman Act) are reproduced at Pet. App. 88a-96a.

STATEMENT OF THE CASE

1. This case concerns an acknowledged split between the Sixth and Eleventh Circuits in two indistinguishable cases addressing the appropriate interplay between the patent and antitrust laws in the ever-recurring context of the settlement of patent infringement litigation. *Compare In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *reh'g denied* (6th Cir. 2003) (Pet. App. 1a) *with Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *reh'g denied* (11th Cir. 2003) (Pet. App. 115a).

Petitioner Andrx Pharmaceuticals, Inc. (Andrx) is a Florida-based generic pharmaceutical company that was sued by a brand pharmaceutical company for seeking to sell a generic version of a brand product, Cardizem CD, in

violation of the brand company's patent rights. When the brand threatened to obtain a preliminary injunction to prevent Andrx from selling generic Cardizem CD, Andrx settled the threatened motion by agreeing to preserve the status quo until the infringement litigation was resolved. Andrx also received payments *pendente lite* and future licensing rights from the brand company. The Sixth Circuit held that this agreement was a *per se* violation of the federal antitrust laws. The Sixth Circuit refused to consider whether the interim settlement was in fact less exclusionary than the lawful exclusionary effect of the patent or indeed whether any anticompetitive effects existed. Pet. App. 17a-21a.

In an indistinguishable case filed by some of the same lawyers and plaintiffs that brought this case, the Eleventh Circuit reached the opposite conclusion on the same issue. Abbott Laboratories sued two generic drug companies for violating its patent rights in connection with the brand drug Hytrin. Abbott obtained agreements to maintain the status quo in exchange for payments and future licenses. The Eleventh Circuit explicitly disagreed with the Sixth Circuit and held that such agreements are lawful and immune from both *per se* and rule of reason scrutiny to the extent they restrain competition to no greater degree than a court might in enforcing the patent. Pet. App. 145a-147a & n.27.

2. This circuit split arose in the context of the patent system's protection of brand-name pharmaceutical products against competition by copycat or generic drugs. The discovery of new drug therapies is dependent on research and development investments undertaken by brand-name pharmaceutical companies. *See* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation*, 35 Cath. U. L. Rev. 433, 435 (1986). These "innovator" companies protect those investments by patenting their inventions. A government-issued patent vests the patent holder with a statutory "right to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. §

154(a)(1). The patentee is also legally authorized to enter into agreements with others (that, but for the patent grant, would be its competitors) dividing the United States into territories in which each may exclusively market the patented product. 35 U.S.C. § 261.

Before marketing a patented drug, brand manufacturers must file a New Drug Application (NDA) and secure approval from the Food and Drug Administration (FDA). 21 U.S.C. § 355(a). The safety and efficacy requirements of that process are so demanding that more than a decade may elapse between the innovator's first synthesis of the drug and its generation of revenues. *See* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation*, 35 Cath. U. L. Rev. 433, 448-49 (1986).

Manufacturers seeking to market a generic drug (one that is "bioequivalent" to a drug already approved by the FDA) may file an **abbreviated** new drug application (ANDA) to demonstrate that the biological effect of the generic version is identical to that of the brand product, and rely on safety and efficacy studies submitted by the brand company in the NDA. 21 U.S.C. § 355(j)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). Because generic companies do not incur all the drug development costs, generic drugs are generally cheaper than their brand-name "pioneer" counterparts. *See United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 & n.1 (1983).

The Hatch-Waxman Act, which created the ANDA mechanism, is designed to protect innovator drug companies' patent rights. *See Eli Lilly*, 496 U.S. at 675-77. To that end, it requires that the ANDA contain a "certification" concerning any unexpired patents covering the brand product. 21 U.S.C. § 355(j)(2)(A)(vii). In a "Paragraph IV" certification, the type of certification relevant here, the ANDA applicant contends that its generic drug will not infringe the patents or that the patents are invalid and unenforceable. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If the

brand company sues the Paragraph IV ANDA applicant for patent infringement within 45 days of the certification notice, the FDA will be barred from granting final approval to the ANDA (even if it otherwise satisfies FDA requirements) for 30 months or until the patent infringement issue is resolved, whichever occurs first. 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2).

FDA approval of a generic drug provides no license to market the product in violation of the brand's valid patents. Indeed, because each sale of the generic product replaces a sale of a more expensive pioneer drug, "a generic applicant's potential liability for lost profits on the brand-name drug usually will vastly exceed its own potential profits after market entry" even before trebling. FTC, *Generic Drug Entry Prior to Patent Expiration*, viii (July 2002) (at www.ftc.gov/os/2002/07/genericdrugstudy.pdf) [hereinafter *FTC Generic Entry Study*]; *see also Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1560-61 (Fed. Cir. 1983); 35 U.S.C. § 284. Given that exposure, the FDA expects "prudent" applicants to wait until the litigation is resolved before marketing and maintains that such prudence "serves the public interest." FDA Proposed Rules: ANDA Regulations, 54 Fed. Reg. 28,872, 28,894 (July 10, 1989); *see FTC Generic Entry Study* at 22-23 (generics do not launch at risk).

3. In 1995, Andrx filed an ANDA seeking permission to market a generic form of Cardizem CD. Cardizem CD was at that time being marketed by Hoechst Marion Roussel, Inc. (HMR), now known as Aventis Pharmaceuticals Inc., which held patents that it claimed covered generic versions of Cardizem CD. These patents are presumed valid. 35 U.S.C. § 282. Andrx submitted a Paragraph IV certification with respect to those patents. In 1996, HMR sued Andrx for patent infringement in the United States District Court for the Southern District of Florida and thereby triggered the 30-month statutory stay of FDA approval. Pet. App. 6a-7a, 97a.

HMR and Andrx both filed potentially dispositive motions, but the patent court issued no rulings and ignored the parties' repeated requests to move the case. *See* Docket Sheet in *Hoechst Marion Roussel, Inc. v. Andrx Pharm., Inc.*, 96 Civ. 06121 (S.D. Fla.). When it appeared that the 30-month stay might expire before the court issued any decision, HMR informed Andrx that it would seek a preliminary injunction to restrain Andrx from marketing generic Cardizem CD upon the stay's expiration. Pet. App. 98a.

Pursuant to their statutory obligations to "cooperate" to expedite the litigation (21 U.S.C. § 355(j)(5)(B)(iii)(III)), HMR and Andrx settled HMR's threatened preliminary injunction through the stipulation and agreement (Stipulation) that is the subject of this case. Pet. App. 97a. HMR agreed not to seek a preliminary injunction, and Andrx agreed to maintain the status quo by not marketing a generic version of Cardizem CD while the patent infringement litigation was pending. HMR also agreed that, if the patent litigation remained unresolved after 18 months or if Andrx lost the patent litigation, Andrx would be entitled to sell its product through a license more than 11 years before the patent's expiration. Pet. App. 99a-100a.

HMR agreed that, if Andrx ultimately prevailed in the patent litigation, it would pay Andrx $100 million for each year that the litigation lasted after Andrx received FDA approval, *i.e.*, a stipulated portion of profits Andrx might have earned had the court hearing the patent case addressed that litigation promptly. In the interim, HMR agreed to pay Andrx $10 million per quarter year until the litigation was resolved; those payments were to be credited against the sum due to Andrx if it prevailed and were to be used to purchase the license if Andrx lost. Pet. App. 100a-102a.

Andrx obtained additional procompetitive concessions under the Stipulation, which increased its ability to ultimately launch a generic version of Cardizem CD. For example, the Stipulation prohibited HMR from amending its labeling

without notice to Andrx (Pet. App. 100a), a tactic brand manufacturers sometimes use to delay FDA approval of generics by forcing generic manufacturers to amend their ANDAs to conform to the new labeling. *See, e.g.*, Naomi Aoki, *Drugmakers Poised for Battle Brand Name Firms Up Stakes In Face of Generic Competition*, Boston Globe, November 26, 2001, at D1. Similarly, the Stipulation defined Andrx's product broadly, so that Andrx would be free to modify its generic version of Cardizem CD without having HMR claim that every modification triggered a new 30-month stay. *See* Pet. App. 110a. Consistent with its desire to market a generic product as soon as prudently possible, Andrx agreed to prosecute its ANDA, thereby assuring HMR a definitive resolution of the patent issues and hastening generic entry. Pet. App. 99a.

The Stipulation avoided a prolonged satellite dispute concerning a preliminary injunction. Nonetheless, the patent court never took action on the pending dispositive motions and did not move the case even during the many months after the Stipulation was publicly disclosed and the statutory stay remained in effect. Andrx continued to defend the litigation. Spending millions of dollars, it reformulated its generic product to attempt to avoid the HMR patent claims. HMR and Andrx then entered into a final settlement of the patent litigation that prohibited Andrx from selling its original formulation but enabled Andrx to sell its non-infringing reformulation with HMR's covenant not to sue. Upon receiving FDA approval of that reformulated product in 1999, Andrx entered the market. Pet. App. 9a-10a.

4. In March 2000, the Federal Trade Commission (FTC) issued an administrative complaint against Andrx, alleging that the Stipulation delayed Andrx's market entry by eleven months. After an exhaustive investigation, the FTC, in April 2001, settled the matter, stating publicly:

> Based on the FTC's investigation, **it does not appear that there was any delay in the entry**

> **into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD.**

FTC, *Hoechst Marion Roussel, Inc., et al.: Analysis to Aid Public Comment*, 66 Fed. Reg. 18636, 18638 (April 10, 2001) (emphasis added).

5. During the pendency of the FTC investigation, various putative classes of consumers and direct purchasers, as well as individual direct purchasers (the Plaintiffs), filed private actions alleging that the Stipulation violated the antitrust laws. The private actions were consolidated for multidistrict proceedings in the United States District Court for the Eastern District of Michigan. On Plaintiffs' motion for partial summary judgment, the district court declared the Stipulation *per se* illegal. The United States Court of Appeals for the Sixth Circuit granted leave to appeal the issue on interlocutory review pursuant to 28 U.S.C. § 1292(b). Pet. App. 83a-85a. The Sixth Circuit agreed with the district court that the Stipulation is *per se* illegal. Pet. App. 4a.

REASONS FOR GRANTING THE PETITION

This Court should grant certiorari to resolve the stark split between decisions of the Sixth and Eleventh Circuits regarding the antitrust liability that may attach to patent infringement settlements. In both cases, a patent holder sued an alleged infringer and sought injunctive relief. In both cases, the patentee and the alleged infringer reached a temporary settlement in which the alleged infringer agreed not to enter the market until the infringement issue was resolved. In both, the alleged infringer received consideration. The Sixth Circuit held that the agreement in this case (the Stipulation) was *per se* unlawful. It declared that the absence of anticompetitive effects and presence of procompetitive benefits were "irrelevant," and it refused to

consider whether the Stipulation was a reasonable settlement of a bona fide infringement claim and whether, in the absence of the Stipulation, the patentee would be legally entitled to exclude the infringer from the market. On what Plaintiffs correctly characterize as "identical facts," the Eleventh Circuit squarely rejected the assertion that such an agreement is *per se* unlawful. To the contrary, the Eleventh Circuit held that such agreements are *per se lawful* to the extent that they achieve no more than the patentee might have otherwise obtained through a court judgment.

The issue dividing the Sixth and Eleventh Circuits is certain to recur. Other pending antitrust challenges to patent infringement settlements have already reached the lower courts and one is presently being appealed to the Second Circuit. Moreover, especially in view of the conflict in the circuits, parties to intellectual property disputes need immediate guidance regarding whether antitrust liability may attach to their settlements because it is common for intellectual property disputes to be settled by agreements in which the infringer receives consideration in exchange for a promise to withhold its product from the market. The need for guidance is particularly acute because this Court has not examined the antitrust implications of any patent infringement settlement in over 40 years. *See United States v. Singer Mfg. Co.*, 374 U.S. 174, 190 (1963) (analyzing facts in detail before concluding that "settlement" was a sham); *see also* H. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 Geo. Mason L. Rev. 359, 368 (2002).

The decision below implicates fundamental antitrust principles and seriously erodes the value of intellectual property. The Sixth Circuit failed to follow decades of Supreme Court jurisprudence concerning when *per se* condemnation is appropriate. Moreover, were *per se* condemnation appropriate under this Court's precedents,

then, contrary to the patent law's constitutionally-based guarantee, patent holders would have no right to exclude infringers; they would merely have the right to *try* to exclude them by filing lawsuits. If the settlement of an issue can be condemned as *per se* unlawful where litigating it would foreclose competition even further, competition policy will be seriously undermined. This Court should resolve the circuit split and hold that embroiling federal patent courts in every patent settlement is not necessary to upholding them and that i) the rule of reason governs agreements, such as the Stipulation, in which an alleged infringer promises to abide by an intellectual property owner's demand for injunctive relief, and ii) settlements that go no further than what the patentee could have secured in litigation are immune from subsequent antitrust challenges.

I. This Court Should Grant Certiorari To Resolve the Conflict Between the Sixth and Eleventh Circuits

As the Plaintiffs in this case have themselves recognized, there is a split in the circuits regarding whether an alleged patent infringer may agree to remain out of the market pending patent litigation in exchange for consideration from the patentee. *See Valley Drug Co. v. Abbott Labs.*, No. 02-12091-J, Appellees' Petition for Rehearing En Banc at 1-2 (11th Cir. Oct. 6, 2003) (arguing for Eleventh Circuit *en banc* review in light of the fact that such an agreement "has been expressly condemned, on **identical** facts, as *per se* unlawful by the Court of Appeals for the Sixth Circuit") (emphasis added).[1] The Sixth Circuit, in this case, and the Eleventh Circuit, in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *reh'g denied* (11th Cir. 2003) (Pet. App. 115a), reached opposite conclusions on identical questions arising from indistinguishable facts.

---

[1] With one exception, the Plaintiffs in this case are also appellees in the Eleventh Circuit litigation.

In both cases, generic manufacturers agreed to keep any bioequivalent product off the market until the patent litigation was resolved or a future license right was triggered. Pet. App. 8a, 124a-125a. Both decisions arose from multidistrict class actions. *In re Cardizem CD Antitrust Litig.*, 1999 U.S. Dist. LEXIS 9285 (J.P.M.L. 1999); *In re Terazosin Hydrochloride Antitrust Litig.*, 1999 U.S. Dist. LEXIS 19640 (J.P.M.L. 1999). Both cases involved consideration given by a patent holder to an alleged infringer, sometimes mischaracterized as "reverse" or "exit" payments. (In *Cardizem*, HMR paid Andrx $40 million per year until the resolution of the patent litigation. Pet. App. 8a. In *Valley Drug*, Abbott paid Geneva $54 million per year until the patent litigation ended and Zenith $12-24 million per year until Abbott's patent expired. Pet. App. 125a-126a.) In both, the district courts granted the plaintiffs' partial summary judgment motions, concluding that the agreements were unlawful *per se*. Pet. App. 13a-14a, 127a. In both, the question on appeal was whether to apply the *per se* rule.

The Sixth Circuit disposed of the issue in a few paragraphs. Pet. App. 17a-21a. It asserted: "There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade." Pet. App. 18a. It dispensed with the patentee's right to exclude Andrx from the market in one sentence: "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." Pet. App. 19a (footnote and citation omitted). As to Andrx's contention that the exclusionary effect of the Stipulation was, if anything, narrower than that of HMR's patent, the court responded, Andrx's "claims that the [Stipulation] lacked anticompetitive effects and had

procompetitive benefits are **simply irrelevant**." Pet. App. 19a-20a (emphasis added).

The Eleventh Circuit acknowledged that "[t]he terms of the agreements at issue in the *Cardizem* case were similar to the terms of the Agreements in this case," but took "the opposite view." Pet. App. 145a & n.25. After an extensive analysis and discussion, it held that under the antitrust laws restraints are generally tested under the rule of reason, that *per se* condemnation is reserved for those rare restraints that are "obviously anticompetitive," and that, even under a *per se* analysis the court must form a judgment about "the competitive significance of the restraint at issue." Pet. App. 132a. With this framework in mind, the court concluded: "If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent." Pet. App. 133a. The court held that because the generic companies' agreements to remain out of the market "appear[] to be no broader than the potential exclusionary effect of the '207 patent" they fall within "the heart of the patent right and cannot trigger the per se label." Pet. App. 135a-136a.

The Eleventh Circuit considered the patentee's payments irrelevant:

> If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. . . . To hold that an ostensibly reasonable settlement of patent litigation gives rise to per se antitrust liability would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a per se rule would be an appropriate

> accommodation of the competing policies of the patent and antitrust laws.

Pet. App. 143a. The Eleventh Circuit expressly recognized the circuit split, concluding "we respectfully disagree."

> We recognize that the Sixth Circuit appeared to take the opposite view . . . . When the exclusionary power of a patent is implicated, however, the antitrust analysis cannot ignore the scope of the patent exclusion. "The protection of the patent laws and the coverage of the antitrust laws are not separate issues." [*United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981).] As the above discussion indicates, we do not think that a payment from the patentee . . . should be automatically condemned under the antitrust laws.

Pet. App. 145a-146a & n.26. The court then rejected both *per se* and rule of reason treatment; the court held that a patent infringement settlement is necessarily lawful under the antitrust laws if the restraint that it imposes on an alleged infringer is no greater than the restraint that the patentee could plausibly secure from a court. Pet. App. 147a & n.27.

II. If the Circuit Split Is Not Resolved, the Lower Courts Will Continue To Apply Radically Inconsistent Rules to Patent Settlements

A. Other Antitrust Challenges to Patent Infringement Settlements Will Soon Reach the Appellate Courts

Without this Court's intervention, the issue that divided the Sixth and Eleventh Circuits will recur. Indeed, a number of antitrust challenges to patent infringement settlements have already resulted in district court decisions that will soon be reviewed by the Courts of Appeals for the District of Columbia Circuit, Second Circuit, and Seventh Circuit.

In a survey of the pharmaceutical industry, the FTC identified many agreements indistinguishable from those addressed in *Cardizem* and *Valley Drug*. *See FTC Generic Entry Study*. Some of these agreements are currently being challenged by competitors, purchasers in multidistrict litigation, and the FTC staff in administrative proceedings. *See Asahi Glass Co. v. Pentech Pharm., Inc.*, ___ F. Supp. 2d ___, 2003 WL 22462405 (N.D. Ill. Oct. 29, 2003); *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003), *appeal docketed sub nom. Tamoxifen Citrate v. Barr Labs., Inc.*, No. 03-7641 (2d Cir. June 20, 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) ("*Cipro*"); *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2002 WL 1488085 (ALJ Decision June 27, 2002); *see also* FTC, *Bristol-Myers Squibb Co.: Analysis to Aid Public Comment*, 68 Fed. Reg. 12080, 12081-82 (March 13, 2003) (describing FTC's complaint regarding agreement in which the generic company abandoned its patent challenge and conceded the patent's validity in exchange for a $72.5 million payment by the brand company). These cases will lead to more appeals on the precise question at issue here.

In *Asahi*, Judge Posner (of the Seventh Circuit, sitting by designation), held that a patent litigation settlement cannot be condemned based on the presence of "reverse" compensation, especially where it may have "led to increased competition." *Asahi*, 2003 WL 22462405 at *6.[2] Judge Posner criticized the Sixth Circuit's *per se* condemnation of "reverse payments," noting that "if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent." *Id.*

---

[2] We note that Judge Posner is the author of many leading scholarly works on antitrust law. *See, e.g.*, Richard A. Posner, *Antitrust Law* (2d ed. 2001); Richard A. Posner, *Antitrust and the New Economy*, 68 Antitrust L.J. 925 (2001).

Judge Posner added: "A ban on reverse-payment settlements would **reduce** the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought **anti**competitive." *Id.* (emphasis added). He then observed that "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Id.* (emphasis in original).

In *Tamoxifen*, the district court dismissed claims alleging that the brand company's payment of $21 million to a generic company that agreed to vacate a judgment of invalidity, keep its own generic off the market, and sell a more expensive licensed version instead, violated the Sherman Act. *Tamoxifen*, 277 F. Supp. 2d at 125-26. The *Tamoxifen* plaintiffs have appealed to the Second Circuit, where a motion to transfer the appeal to the Federal Circuit has been referred to the merits panel. *Tamoxifen Citrate v. Barr Labs., Inc.*, No. 03-7641 (2d Cir. June 20, 2003).

In *Cipro*, the district court held that it was not a *per se* violation of the Sherman Act for a brand company to pay $398 million for an agreement to keep a generic product off the market. *Cipro*, 261 F. Supp. 2d at 196. The *Cipro* court rejected the plaintiffs' contention that "reverse payments" render a patent infringement settlement *per se* illegal and noted that "even in the traditional context, implicit consideration flows from the patent holder to the alleged infringer." *Id.* at 252. The *Cipro* court concluded that "when patents are involved, case law directs that the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal." *Id.* at 249.

In *Schering-Plough,* the FTC staff argued that "reverse payments" are *per se* unlawful, but the FTC Administrative

Law Judge (ALJ) rejected that approach because it would have inappropriately required the court to presume that the patent infringement suit lacked merit and involved application of a *per se* rule to a new practice. *Schering-Plough*, 2002 WL 1488085 at 3, 65, 67. The ALJ concluded that a brand payment does not take a patentee "beyond the rights conferred by the patent" and held that, "because an agreement to settle patent litigation must be examined in the context in which the agreement arose, the *per se* approach is not appropriate" *Id.* at 64, 67. On appeal to the full Commission, the staff has argued that the Commission should follow the *Cardizem per se* holding, which the FTC staff described as arising from an agreement "similar" to those in *Schering-Plough*. *See In re Schering-Plough*, Appeal Brief Of Counsel Supporting the Complaint at 42, August 9, 2002 (2002 WL 1941700). The staff's appeal is pending. *See* FTC Docket 9297 (at www3.ftc.gov/os/adjpro/d9297/index.htm).

Even were the issue limited to the pharmaceutical industry, it would not end with *Cardizem*, *Valley Drug*, *Asahi*, *Tamoxifen*, *Cipro*, and *Schering-Plough*. The use of brand payments (*i.e.*, consideration) has been a widespread pharmaceutical industry practice affecting many products generating billions of dollars in total annual revenues. Accordingly, the cottage industry that is now developing to seek antitrust damages for this practice will likely flourish.

Brand payments have been used to settle 50% of resolved patent cases involving "blockbuster" drugs. *See FTC Generic Entry Study* at 26, 28. Even more cases settled using other consideration such as "delayed licenses," which the FTC staff has erroneously condemned as *per se* unlawful using the same reasoning employed in challenges to brand payments. *See id.* at 29, 34; *Schering-Plough*, 2002 WL 1488085 at 64. Brand payments have exceeded $500 million and have resolved challenges to products generating total annual revenues in excess of $4 billion. *See FTC Generic*

Entry Study at 25, 32, 35. One-third of brand companies and 20% of generic companies have used "brand payments" or "delayed licenses." *Id.* at 3, 34.

The current legal uncertainty could affect pharmaceutical products generating as much as $20 billion in annual revenue. *See Valley Drug Co. v. Abbott Labs.*, No. 02-12091-J, Appellees' Petition for Rehearing En Banc at 2 (11th Cir. Oct. 6, 2003). On average, generic drug manufacturers file more than 500 ANDAs per year. *See FTC Generic Entry Study* at 10. In recent years, approximately 20% of those ANDAs contained Paragraph IV certifications challenging brand companies' patent claims. *Id.* These Paragraph IV ANDAs often challenge "blockbuster" drugs that generate billions of dollars in annual revenue for brand companies and finance their innovation efforts. *See id.* at 10-11. In such cases, patent litigation between the brand and generic is a virtual certainty, and the incentives to settle are great. *Id.* at 14, 18. Given the circuit split and likelihood of continued litigation, this Court should grant certiorari.

B. The Issue Is Not Confined to the Pharmaceutical Industry

The circuit split does not merely concern an issue of particular interest to the pharmaceutical industry; it implicates all patent infringement settlements. The payments in *Cardizem* and *Valley Drug* merely highlight the consideration that generally flows to infringers in patent settlements. "Payments" may take various forms (*e.g.*, a release of damages already incurred or a future license). As "payments" by patentees to infringers play a critical role in settling patent litigation generally, the Sixth Circuit's erroneous holding will lead to antitrust suits challenging non-pharmaceutical patent infringement settlements.

In most infringement suits, the alleged infringer causes the intellectual property owner at least some harm before the suit is filed, so that the property owner has "a damages claim to bargain with" during settlement discussions that will

ensure that some consideration flows to the infringer. *See* Pet. App. 143a. A patent holder's release of the infringer from some or all of the patentee's damage claim in exchange for the infringer's promise to exit the market is consideration indistinguishable from a brand payment. *See Asahi*, 2003 WL 22462405 at *6 ("*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement") (emphasis in original); *Cipro*, 261 F. Supp. 2d at 252 ("even in the traditional context, implicit consideration flows from the patent holder to the alleged infringer"); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747, 772 (2003) ("When an infringement plaintiff accepts a discount on the value of its lost-monopoly rent damages claim in exchange for the certainty of recovering some portion of its damages plus the certainty that the allegedly infringing use will cease, it has effectively bought out the possibility of competition that would destroy the value of its patent monopoly. This is no different than if the patentee paid a potential new entrant – and potential infringer – not to enter the market and begin the allegedly infringing conduct.").

Litigants are already beginning to extend the rationale underlying *Cardizem* to its logical but dangerous conclusion. For example, the FTC staff has contended that it is unlawful *per se* for a patentee to share the monopolistic rents generated by a patent through a brand payment **or** through a temporal division of the patent's lifespan. *See* FTC, *Generic Entry Study* at 29, 34; *Schering-Plough*, 2002 WL 1488085 at 64. Thus, using the FTC staff's theory, it is a *per se* violation of the Sherman Act for a patentee and an alleged infringer to settle an infringement suit concerning a patent due to expire in ten years by agreeing that the infringer will remain out of the market for the first five years and receive a royalty-free license to enter the market during the last five years.

Like other types of litigation, 96% of patent infringement cases are resolved before trial, with the vast majority settled. *See* Federal Judicial Caseload Statistics, Table C-4 U.S. District Courts – Civil Cases Terminated, by Nature of Suit and Action Taken, During the 12-Month Period Ending March 31, 2002 (March 31, 2002) (at www.uscourts.gov/caseload2002/contents.html); Gauri Prakash-Canjels, *Trends in Patent Cases: 1990-2000*, 41 IDEA 283, 290-91 (2001). The Sixth Circuit's ban on patent infringement settlements in which the alleged infringer is paid to remain out of the market will turn many of these settlements into *per se* violations of the antitrust laws. This Court should grant review to avert this result, and to clarify the circumstances under which antitrust liability may attach to settlements of intellectual property litigation.

C. The Multidistrict Nature of Antitrust Challenges to Patent Infringement Settlements Exacerbates the Circuit Split

Antitrust litigation challenging patent infringement settlements is typically multidistrict in nature. As a result, disputes will arise throughout the Nation, even within the Sixth and Eleventh Circuits, regarding what law to apply. This is a further reason why this Court's review is urgently needed.

This case provides an example. Andrx is based in Florida, within the Eleventh Circuit. The principal case in this multidistrict litigation was filed in the Southern District of Florida and will return there in a few months when pre-trial proceedings are complete. *See* 28 U.S.C. § 1407; *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). If this Court denies certiorari, the Florida Plaintiffs will likely argue to the Florida trial court that the Sixth Circuit's decision should govern under the law of the case doctrine. But the Florida court would be bound to follow the law of the Eleventh Circuit, as set forth in *Valley Drug*. *See Murphy v. FDIC*, 208 F.3d 959, 966 (11th Cir.

2000). Accordingly, if this Court fails to resolve the conflict in the circuits, the Florida court may find itself "'suspended between the doctrine of stare decisis and the doctrine of law of the case. In such a circumstance the . . . court would invite reversal if it did not follow the decisions of its own court of appeals.'" *Moore v. Valder*, 65 F.3d 189, 195 n.9 (D.C. Cir. 1995) (citation omitted).

Similar scenarios may unfold in *Valley Drug* and the other multidistrict actions arising from antitrust challenges to patent infringement suit settlements. Two *Valley Drug* cases originated in Michigan within the Sixth Circuit. *See* Docket Sheets for *Blue Cross of Michigan v. Abbott Labs.*, 01-CV-95 (W.D. Mich.) and *Bernstein v. Abbott Labs.*, 01-CV-72974 (E.D. Mich.). While the complaints filed there were superseded, the Michigan plaintiffs may well seek a remand and the application of *Cardizem*. Cases consolidated in *Cipro* and *Tamoxifen* also originated in Michigan, within the Sixth Circuit, and Florida, within the Eleventh Circuit. *See* Docket Sheets for *McIntyre v. Bayer AG*, 00-CV-60361 (E.D. Mich.), *Loesch v. Bayer AG*, 00-CV-7738 (S.D. Fla.), *Bennish v. Barr Labs. Inc.*, 00-CV-74949 (E.D. Mich.), *Maloney v. Barr Labs.*, 01-CV-4187 (S.D. Fla.), and *Blonstein v. Barr Labs.*, 01-CV-8399 (S.D. Fla.). Thus, because of the circuit split, there is uncertainty even within the Sixth and Eleventh Circuits, and the potential for further wasteful litigation. The need for this Court's review is, therefore, exceptionally pressing.

III. The Question Presented Is One of Great Importance

The issue that is the subject of the circuit split is one of vital importance to the Nation. At the points where intellectual property and antitrust enforcement intersect, the congressional balance between the interests of innovators, would-be competitors, and consumers must be carefully maintained. *See* Assistant Attorney General R. Hewitt Pate, Antitrust Division, *Antitrust and Intellectual Property*, Address to the American Intellectual Property Law

Association at 3 (2003) [hereinafter *Antitrust & Intellectual Property*](at www.usdoj.gov/atr/public/speeches/200701.pdf) ("Calls for more aggressive antitrust enforcement as a vehicle for cabining the enjoyment of intellectual property rights should . . . be viewed with great caution.").

Blunderbuss application of the judge-made *per se* rule in such circumstances has grave implications for innovation and competition. For example, when patents cannot be readily enforced through settlements, the brand pharmaceutical companies upon which we rely to discover new critical medicines are discouraged from making necessary investments. Pet. App. 143a-144a. In addition, if generic companies cannot be compensated for agreeing to settle their weaker patent infringement challenges, there will be fewer patent challenges and less competition in the long-run. *Asahi*, 2003 WL 22462405 at *6.

While some have challenged this logic – arguing that a *per se* rule is a critical means of protecting consumer access to affordable medicine – there is unanimous agreement that the issue is one of "vital public importance." *Valley Drug Co. v. Abbott Labs.*, No. 02-12091-J, Appellees' Petition for Rehearing En Banc at 2 (11th Cir. Oct. 6, 2003); *see also* then-FTC Chairman Robert Pitofsky, Statement of the FTC Before the House Judiciary Committee at 10 (2000) (at www.ftc.gov/os/2000/04/antitrusttimony.htm) (describing the "drug settlement cases" as "a tremendously important area, with high stakes to consumers").

As applied to the pharmaceutical industry, where there is intense public interest in pharmaceutical innovation and medical costs, the question of whether brand and generic pharmaceutical companies can settle their patent disputes is of such national importance that it has generated widespread media attention. *See, e.g.*, Jayne O'Donnell, *FTC Targets Deal to Keep Generic Off Shelf*, USA Today, Sept. 30, 1999, at Money, 1B (discussing *Cardizem*); Robert Pear, *AARP Wants Bigger Role in Prescription Drug Cases*, N.Y. Times,

April 23, 2002, at A14 (describing issue as "a political minefield" and quoting former FTC official as describing "agreements between brand-name and generic drug manufacturers to settle patent litigation" as the "hottest area in health care antitrust law – indeed, arguably in all of antitrust"); Peter Spiegel, *U.S. To Widen Drug Groups Inquiry: FTC Investigation Could Lead to New Wave of Lawsuits*, Financial Times (London), July 6, 2001, at 17 (discussing FTC investigations of agreements in *Cardizem*, *Valley Drug*, and *Schering-Plough*); Sheryl Gay Stolberg & Jeff Gerth, *Keeping Down the Competition: How Companies Stall Generics And Keep Themselves Healthy*, N.Y. Times, July 23, 2000, Section 1 at page 1 (discussing *Cardizem*).

A. The Sixth Circuit's Decision Upsets the Critical Balance Between the Patent and Antitrust Laws

The Sixth Circuit's decision dispenses with basic principles underlying the patent and antitrust laws. The departure from accepted precepts has grave implications for innovators and patent challengers.

Contrary to the Sixth Circuit's assertion (Pet. App. 19a), a patentee's legal monopoly rights extend beyond bringing good-faith patent infringement actions, seeking preliminary injunctions, and collecting damages from infringers. The patent laws "reward[] innovation with a temporary monopoly." *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002). A patent holder is entitled to a "limited patent monopoly under the Constitution." *Graham v. John Deere Co.*, 383 U.S. 1, 7 (1966). It is not a mere ticket to enter a courthouse and seek judicial relief for infringement. The government-issued patent itself – not the court order enforcing it – is the "grant of an exclusive right to an invention," *id.* at 9, "expressly sanctioned by the Constitution." *Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313, 330 & n.20 (1971). Indeed, Congress has explicitly provided that, even without

further taxing the scarce resources of the federal courts, a patent holder has a statutory "right to exclude others from making, using, offering for sale, or selling the invention," and may use licensing arrangements to enter into what in other contexts would be condemned as unlawful horizontal market allocation agreements. *See* 35 U.S.C. §§ 154(a)(1), 261.

The Sixth Circuit's assumption that these principles can be ignored when assessing the legality of a patent infringement settlement under the antitrust laws is incorrect. The Sherman Act only prohibits *unreasonable* restraints of trade. *Business Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 723 (1988). Generally, the reasonableness of a restraint on trade must be analyzed under a rule of reason requiring an assessment and weighing of anticompetitive and procompetitive effects. *Id.* at 726. The only exceptions are in those narrow circumstances in which "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets" such that a form of truncated analysis, including the *per se* rule's outright ban, may be employed. *California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999).

The Sixth Circuit erred in condemning the Stipulation as *per se* illegal without any inquiry into whether, in light of HMR's patent, it was actually anticompetitive in any respect, and without regard to its procompetitive benefits. This Court has recently explained that, before determining "whether the experience of the market" is such that "a confident conclusion about the principal tendency of a restriction" can be reached without a rule of reason analysis, the court must consider "the circumstances, details, and logic of [the] restraint" and reach conclusions about "whether the effects **actually are anticompetitive**." *California Dental*, 526 U.S. at 775 n.12, 781 (emphasis added). As Judge Easterbrook has explained: "The question whether a restraint is 'naked'

requires some knowledge of its effects. . . . In recent years, the *per se* inquiry has required more and more economic exposition. There is no longer any real 'shortcut' to condemnation." Frank H. Easterbrook, *The Limits of Antitrust*, 63 Texas L. Rev. 1, 18-19 (1984); *see also Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 297-98 (1985) (requiring for *per se* characterization a "satisfactory threshold determination whether anticompetitive effects would be likely"). Given that "assumption alone will not do," *California Dental*, 526 U.S. at 775 n.12, the Sixth Circuit should have, at a minimum, considered "the strength of the patent" (*Asahi*, 2003 WL 22462405 at *4), evaluated the foreclosure that flowed from the valid exercise of the patentee's patent rights, and considered the FDA's determination that prudent generics have never entered at risk and the FTC's determination that the very Stipulation under consideration did not lead to "any delay in the entry into the market of a generic version of Cardizem CD," *see* 66 Fed. Reg. 18636, 18638 (April 10, 2001) – rather than ignoring all of this as "irrelevant." Pet. App. 19a-20a.

This Court's directive to consider actual anticompetitive effects is particularly important when dealing with patent settlements. When an antitrust case "concerns articles protected by letters patent," the patentee's monopoly rights must be the "first important and most material fact." *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 88 (1902). Antitrust law must accommodate the monopolies created by our intellectual property laws because intellectual property – such as patented medicines – "exists at all only because of [those] laws." *BMI v. CBS*, 441 U.S. 1, 18-20 (1979).

It follows from the antitrust law's accommodation of intellectual property rights that an owner of intellectual property must be able to enter into "any market arrangements reasonably necessary to effectuate the rights that are granted"

without being deemed to have engaged in "a *per se* violation of the Sherman Act." *See BMI*, 441 U.S. at 18; *see also B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426-27 (Fed. Cir. 1997) (restraints allegedly exceeding "scope of the patent" "must be evaluated under the rule of reason"); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) (question is "whether the patentee has ventured beyond the patent grant and into behavior having an anticompetitive effect not justifiable under the rule of reason"). This includes a "settlement by agreement, rather than litigation," to resolve "legitimately conflicting claims or threatened [patent] interferences"; an arrangement that this Court has held "is not precluded by the [Sherman] Act." *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

The Stipulation was an interim settlement, "reasonably necessary to effectuate" HMR's patent rights. Accordingly, it should have been evaluated under the rule of reason. *See BMI*, 441 U.S. at 18. If such a settlement could be condemned *per se*, without any consideration of the exclusionary impact of the patent, consumers could seek antitrust damages resulting from their inability to purchase patent-infringing products. If, as the *per se* ruling suggests, antitrust policy is used to promote **infringing** competition, there will be diminished innovation and fewer new products to protect. *See In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000) (court must give "'due consideration to the exclusivity that inheres in the patent grant'"), *cert. denied*, 531 U.S. 1143 (2001); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) ("some measure must guarantee that the jury account for the procompetitive effects and statutory rights extended by the intellectual property laws") (internal quotation omitted).

It is for this Court, not Congress, to correct the Sixth Circuit's error about the type of antitrust analysis that should govern patent infringement settlements. The *per se* rule is "a judicial gloss" on the Sherman Act; the statute, after all, only

condemns unreasonable restraints. *See Continental T.V. v. GTE Sylvania*, 433 U.S. 36, 49-50 (1977). Since "[i]t was the courts, not the Congress, that created the concept of per se rules" and "a rule of reason," it "has historically been the role and function of the Supreme Court" to determine which method to apply in particular types of cases. *See* William F. Baxter, *Vertical Practices*, 52 Antitrust L.J. 743, 751 (1983). This Court should grant certiorari to clarify that it is not a *per se* violation of the antitrust laws for a patentee to protect its patent rights by paying a patent infringer to remain out of the market during the life of the patent.

B. The Sixth Circuit's Decision Devalues Intellectual Property Rights

If a patentee may not "bolster" a patent grant with a payment to an infringer to induce compliance with the statutory monopoly without incurring antitrust liability, it follows that the statutory "right to exclude others," 35 U.S.C. § 154(a)(1), has no practical value to a patentee until a court enforces it, and that the patent is devalued by the costs and risks of litigation. Recognizing the implications of such a holding, major associations of intellectual property owners, such as the American Intellectual Property Law Association and the Intellectual Property Owners Association, have argued that, payments by patentees notwithstanding, intellectual property settlements should be reviewed under the rule of reason. *See* AIPLA, *Testimony Before FTC and Antitrust Division on Antitrust & Intellectual Property Issues* 9) (April 10, 2002) (at www.ftc.gov/os/comments/intelpropertycomments) (observing that the district courts in *Cardizem* and *Valley Drug* "held settlement agreements illegal under a *per se* rule" and arguing that "applying a *per se* rule to litigation settlements is unwise and inappropriate"); IPO, *Comments on the Joint Hearings of the FTC and DOJ Regarding Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* 10 (Nov. 15, 2002) (at www.ftc.gov/os/comments/intelpropertycomments)

("Central to the legitimacy of [intellectual property] settlements is the issue of whether the alleged infringer would be able to compete absent a license. In order to apply a *per se* rule to an intellectual property settlement, a court must, in effect, assume that the intellectual property owner would lose the infringement suit – an assumption that no court is entitled to make without a trial of the infringement issue, or a finding of clear and convincing evidence to overcome the statutory presumption of validity of issued patents. For these reasons, we believe that, absent a fraudulent intellectual property right or a sham lawsuit or settlement, intellectual property settlements should be analyzed under the rule of reason.") .

The damage inflicted by the Sixth Circuit's decision on incentives to innovate is particularly acute in the pharmaceutical industry. Indeed, since the first patent infringement settlement was condemned as *per se* unlawful by the district court in *Cardizem*, the prime indicator of pharmaceutical innovation has declined steadily from its peak in 2000 by 5%-9% every year. *See IND Filings Hit Seven-Year Low in 2003; Where is R&D Productivity,* Prescription Pharma. & Biotechnology ("The Pink Sheet") 8 (Nov. 10, 2003). It is likely that brand companies' inability to settle patent infringement suits is contributing to the current "research slump." *See* Matthew Herper, *Solving the Drug Patent Problem,* Forbes.com (May 2, 2002) (at www.forbes.com/2002/05/02/0502patents.html) (arguing that slump is attributable to "long battles over dozens of patents" that "distract pharmaceutical companies from their job: making new medicines"). Given the importance of patents to the industry, the Pharmaceutical Research and Manufacturers of America have joined the other intellectual property owners in opposing a *per se* ban on payments by patent holders to infringers in patent settlements. *See* PhMRA, *Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights* 38 (April 22, 2002) (at www.ftc.gov/os/comments/

intelpropertycomments) ("Unless the underlying infringement claim is objectively baseless or the settlement would produce a result outside the spectrum of possible litigation outcomes, settlements should not be subject to antitrust liability."); *see also In re: Cardizem CD Antitrust Litig.*, No. 00-2482, Brief of Amicus Curiae PhMRA (6th Cir. April 16, 2000); *In re: Cardizem CD Antitrust Litig.*, No. 00-2482, Brief of Amicus Curiae Generic Pharm. Ass'n (6th Cir. April 16, 2000).

C. The Issue Has Been Fully Debated and Is Ripe For Resolution

For the past five years, the antitrust enforcement agencies and the antitrust scholars have debated whether patentee payments in patent infringement settlements should be *per se* unlawful or evaluated under the rule of reason. Indeed, the question of how the antitrust law should accommodate intellectual property interests has been at the forefront of discussions in that community. *See generally* Assistant Attorney General R. Hewitt Pate, *Antitrust & Intellectual Property* at 1 (the intersection of antitrust and intellectual property is the "'issue du jour' among antitrust practitioners"). The debate has run its course, and this Court's intervention is now needed.

The Department of Justice's Antitrust Division never sought a *per se* ban. This year, it stated that enforcement actions would continue to account for exclusionary effects of patents and procompetitive benefits of settlements:

> These [Hatch-Waxman] cases present especially tough problems for [antitrust] enforcers. First, these cases occur in the context of conduct the law generally favors – the settlement of litigation. Second, **assessing the competitive significance of settlements often depends on an evaluation of the underlying strength of patent rights**. If a patent is valid and infringed, then any competitive entry allowed by a

> settlement is up to the patent holder. If a patent is invalid and not infringed, then there should be no impediment to competitive entry whatsoever.

Id. at 12 (emphasis added).

While the FTC staff has sought a *per se* ban, the Commission has proceeded more cautiously, authorizing an extensive study of brand-generic patent litigation settlements based on an industry survey. *See generally FTC Generic Entry Study*. Several FTC Commissioners debated the issue publicly. For example, Commissioner Leary stated that he would be "tempted to support a presumption that reverse payments are illegal," but "would not suggest at this stage that the presumption be conclusive (which would be another way of saying reverse payments are illegal *per se*)." Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Part II*, 5 (2001) (at www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm). On the other hand, then-Commissioner Anthony argued that, because "settlements between monopolists and would-be entrants are ripe for collusive dealings," "[p]atent litigation, which tests and reveals the validity of a patent, should be allowed to run its course." Sheila F. Anthony, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property* 4-6 (2000) (at www.ftc.gov/speeches/anthony/sfip000601.htm).

Leading antitrust scholars (including Judge Posner, *see Asahi*, 2003 WL 22462405) have also weighed in, maintaining that *per se* treatment is inappropriate. *See, e.g.*, Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, Antitrust Bull. 491, 539 (Summer-Fall 2002) ("these settlements cannot be characterized as naked market allocation schemes and, therefore, are not ripe for *per se* treatment"); Yee Wah Chin & Thomas G. Krattenmaker, *Antitrust Update*, M&A Tax J. 30, 38 (December 2001) ("appropriate test of the legality under the antitrust laws of such arrangements settling

intellectual property disputes should not be a *per se* test"); Thomas F. Cotter, *Refining the "Presumptive Illegality": Approach to Settlements of Patent Disputes Involving Reverse Payments*, 87 Minn. L. Rev. 1789, 1802 (2003) ("*per se* treatment of reverse payment settlements is inappropriate, because these agreements also have some potential to enhance rather than impede efficiency"); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747, 797 (2003) ("Exit payments should . . . be permitted when the patentee's claims appear *ex ante* to have substantial merit and disallowed when they are likely to fail."); James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 Antitrust L. J. 777, 806 (2003) ("existence of procompetitive reasons for partial settlement payments from brand-name manufacturers to the generics indicates that a strict *per se* illegal treatment of such payments is inappropriate"); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, 17 Antitrust 68, 75 (Spring 2003) (Hatch-Waxman settlements should be analyzed under a "rule of reason analysis, which begins by measuring the patent").[3]

Given the extent of the public discourse that these agreements have generated over the past five years, the issue is now ripe for this Court's review. This Court should grant certiorari to consider whether *per se* antitrust enforcement of

---

[3] Others have argued in favor of a *per se* ban. *See, e.g.*, Keith Leffler & Cristopher Leffler, *The Probabilistic Nature of Patent Rights*, 17 Antitrust 77, 78 (Summer 2003); Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 Minn. L. Rev. 1767, 1781-82 (2003); Peter J. Prommer, *Note: The Pioneer and Generic Drug Manufacturer Agreements: Is the Sherman Act Big Enough to Swallow These Pills?*, 2002 J. L. Tech. & Pol'y 215, 232-33 (Spring 2002).

intellectual property settlements will undermine the objectives Congress sought to achieve in the patent laws.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Louis M. Solomon,
Counsel of Record
Claude M. Millman
PROSKAUER ROSE LLP
1585 Broadway
New York, NY 10036
(212) 969-3000 (voice)
(212) 969-2900 (fax)

DAVID A. STRAUSS
1111 East 60th Street
Chicago, IL 60637
(773) 702-9601 (voice)

Counsel for Petitioner

November 21, 2003

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 00-2483

In Re: CARDIZEM CD ANTITRUST LITIGATION,
LOUISIANA WHOLESALE DRUG CO., ET AL.,

Plaintiffs-Appellees,

—v.—

HOECHST MARION ROUSSEL, INC.,
and ANDRX PHARMACEUTICALS, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the
Eastern District of Michigan at Detroit.

No. 99-01278—Nancy G. Edmunds, District Judge.

Argued: April 30, 2002

Decided and Filed: June 13, 2003

Before:

SILER and CLAY, *Circuit Judges*;
OBERDORFER, *District Judge*.*

OBERDORFER, District Judge. This antitrust case arises out of an agreement entered into by the defendants, Hoescht Marion Roussel, Inc. ("HMR"), the manufacturer of the prescription drug Cardizem CD, and Andrx Pharmaceuticals, Inc. ("Andrx"), then a potential manufacturer of a generic version of that drug. The agreement provided, in essence, that Andrx, in exchange for quarterly payments of $10 million, would refrain from marketing its generic version of Cardizem CD even after it had received FDA approval (the "Agreement"). The plaintiffs are direct and indirect purchasers of Cardizem CD who filed complaints challenging the Agreement as a violation of federal and state antitrust laws. After denying the defendants' motions to dismiss, *see In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) ("Dist. Ct. Op. I") and granting the plaintiffs' motions for partial summary judgment, *id.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000) ("Dist. Ct. Op. II"), the district court certified two questions for interlocutory appeal:

> (1) . . . In determining whether Plaintiffs have properly pled antitrust injury, does the language of the Sixth Circuit's decisions in *Valley Products Co. v. Landmark*, 128 F.3d 398, 404 (6th Cir. 1997) and *Hodges v. WSM, Inc.*, 26 F.3d 36, 39 (6th Cir. 1994) require dismissal of Plaintiffs' antitrust claims at

---

* The Honorable Louis F. Oberdorfer, United States District Judge for the District of Columbia, sitting by designation.

> the pleading stage if Plaintiffs cannot allege facts showing that Defendants' alleged anticompetitive conduct was a "necessary predicate" to their antitrust injury; *i.e.*, that dismissal is required unless Plaintiffs plead facts showing that the alleged antitrust injury could not possibly have occurred absent Defendants' alleged anticompetitive conduct?
>
> (2) . . . In determining whether Plaintiffs' motions for partial judgment were properly granted, whether the Defendants' September 24, 1997 Agreement constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and under the corresponding state antitrust laws at issue in this litigation.

JA 607. Our answers, explained more fully herein, are as follows:

Answer to First Certified Question: As framed, the certified question is not susceptible to a yes or no answer because it incorporates a definition of "necessary predicate" that we reject. *Hodges* and *Valley Products* stand for the proposition that in order to survive a motion to dismiss for failure to allege antitrust injury, a plaintiff must allege that the antitrust violation is *either* the "necessary predicate" for its injury *or* the only means by which the defendant could have caused its injury. Under the "necessary predicate" option, dismissal is warranted only where it is apparent from the allegations in the complaints that the plaintiffs' injury would have occurred even if there had been no antitrust violation. Here, Andrx could have made a unilateral and legal decision to delay its market entry, but the plaintiffs have alleged it would not have done so but for the Agreement and HMR's payment to it of $40 million per year. The

plaintiffs' allegations satisfy the "necessary predicate" test. The defendants' claim that Andrx's decision to stay off the market was motivated not by the $40 million per year it was being paid by HMR, but by its fear of damages in the pending patent infringement litigation, merely raises a disputed issue of fact that cannot be resolved on a motion to dismiss. Accordingly, the district court properly denied the defendants' motions to dismiss for failure to allege antitrust injury.

Answer to Second Certified Question: Yes. The Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem CD and its generic equivalents is a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws. Accordingly, the district court properly granted summary judgment for the plaintiffs on the issue of whether the Agreement was *per se* illegal.

I. BACKGROUND

As the district court has set forth a complete outline of the relevant statutory framework, *see* Dist. Ct. Op. I, at 627-29; Dist. Ct. Op. II, at 685-86, facts, *see* Dist. Ct. Op. I, at 629-32; Dist. Ct. Op. II, at 686-89, and procedural history, *see* Dist. Ct. Op. I, at 632-33; Dist. Ct. Op. II, at 689-90, we repeat here only what is necessary to our analysis of the issues on appeal.

A. Statutory Framework

In 1984, Congress enacted the Hatch-Waxman Amendments, *see* Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399. Those amendments permit a

potential generic[1] manufacturer of a patented pioneer drug to file an abbreviated application for approval with the Food and Drug Administration ("FDA") (known as an Abbreviated New Drug Application ("ANDA")). *See* 21 U.S.C. § 355(j)(1). Instead of submitting new safety and efficacy studies, an ANDA may rely on the FDA's prior determination, made in the course of approving an earlier "pioneer" drug, that the active ingredients of the proposed new drug are safe and effective. *Id.* § 355(j)(2)(A). Every ANDA must include a "certification that, in the opinion of the applicant and to the best of his knowledge, the proposed generic drug does not infringe any patent listed with the FDA as covering the pioneer drug." *Id.* § 355(j)(2)(A)(vii). That certification can take several forms. Relevant here is the so-called "paragraph IV certification" whereby the applicant certifies that any such patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(j)(2)(A)(vii)(IV). An applicant filing a paragraph IV certification must give notice to the patent-holder, *id.* § 355(j)(2)(B); the patent-holder then has forty-five days to file a patent infringement action against the applicant. *Id.* § 355(j)(5)(B)(iii). If the patent-holder files suit, a thirty-month stay goes into effect, meaning that unless before that time the court hearing the patent infringement case finds that the patent is invalid or not infringed, the FDA cannot approve the generic drug before the expiration of that thirty-month period. *Id.* § 355(j)(5)(B)(iii)(I). In order to encourage generic

---

[1] A "generic" drug contains the same active ingredients but not necessarily the same inactive ingredients as a "pioneer" drug sold under a brand name. *United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 (1983).

entry, and to compensate for the thirty-month protective period accorded the patent holder, the first generic manufacturer to submit an ANDA with a paragraph IV certification receives a 180-day period of exclusive marketing rights, during which time the FDA will not approve subsequent ANDA applications. *Id.* § 355(j)(5)(B)(iv). The 180-day period of exclusivity begins either (1) when the first ANDA applicant begins commercial marketing of its generic drug (the marketing trigger) or (2) when there is a court decision ruling that the patent is invalid or not infringed (the court decision trigger), whichever is earlier. *Id.*

B. Facts

Unless otherwise noted, the following facts are undisputed. HMR manufactures and markets Cardizem CD, a brand-name prescription drug which is used for the treatment of angina and hypertension and for the prevention of heart attacks and strokes. The active ingredient in Cardizem CD is diltiazem hydrochloride, which is delivered to the user through a controlled-release system that requires only one dose per day. HMR's patent for diltiazem hydrochloride expired in November 1992.

On September 22, 1995, Andrx filed an ANDA with the FDA seeking approval to manufacture and sell a generic form of Cardizem CD. On December 30, 1995, Andrx filed a paragraph IV certification stating that its generic product did not infringe any of the patents listed with the FDA as covering Cardizem CD. Andrx was the first potential generic manufacturer of Cardizem CD to file an ANDA with a paragraph IV certification, entitling it to the 180-day exclusivity period once it received FDA approval.

In November 1995, the United States patent office issued Carderm Capital, L.P. ("Carderm") U.S. Patent

No. 5,470,584 (" '584 patent"), for Cardizem CD's "dissolution profile," which Carderm licensed to HMR. JA 1796-1810. The dissolution profile claimed by the '584 patent was for 0-45% of the total diltiazem to be released within 18 hours ("45%-18 patent").[2]

In January 1996, HMR and Carderm filed a patent infringement suit against Andrx in the United States District Court for the Southern District of Florida, asserting that the generic version of Cardizem CD that Andrx proposed would infringe the '584 patent. *See* JA 1240-1257 (Complaint, *Hoescht Marion Roussel, Inc. v. Andrx Pharmaceuticals, Inc.*, No. 96-06121 (S.D. Fla. filed Jan. 31, 1996)). The complaint sought neither damages nor a preliminary injunction. *Id.* However, filing that complaint automatically triggered the thirty-month waiting period during which the FDA could not approve Andrx's ANDA and Andrx could not market its generic product. In February 1996, Andrx brought antitrust and unfair competition counterclaims against HMR. JA 1717-47. In April 1996, Andrx amended its ANDA to specify that the dissolution profile for its generic product was not less than 55% of total diltiazem released within 18 hours ("55%-18 generic"). HMR nonetheless continued to pursue its patent infringement litigation against Andrx in defense of its 45%-18 patent. On June 2, 1997, Andrx represented to the patent court that it intended to market its generic product as soon as it received FDA approval. JA 1758.

On September 15, 1997, the FDA tentatively approved Andrx's ANDA, indicating that it would be finally approved as soon as it was eligible, either upon expiration of the thirty-month waiting period in early July

---

[2] Two other patents for the dissolution profile of Cardizem CD had previously been issued, one in February 1994 and one in August 1995. Neither is relevant to the present litigation.

1998, or earlier if the court in the patent infringement action ruled that the '584 patent was not infringed.

Nine days later, on September 24, 1997, HMR and Andrx entered into the Agreement. JA 1363-73. It provided that Andrx would not market a bioequivalent or generic version of Cardizem CD in the United States until the earliest of: (1) Andrx obtaining a favorable, final and unappealable determination in the patent infringement case; (2) HMR and Andrx entering into a license agreement; *or* (3) HMR entering into a license agreement with a third party. Andrx also agreed to dismiss its antitrust and unfair competition counterclaims, to diligently prosecute its ANDA, and to not "relinquish or otherwise compromise any right accruing thereunder or pertaining thereto," including its 180-day period of exclusivity. In exchange, HMR agreed to make interim payments to Andrx in the amount of $40 million per year, payable quarterly, beginning on the date Andrx received final FDA approval.[3] HMR further agreed to pay Andrx $100 million per year,[4] less whatever interim payments had been made, once: (1) there was a final and unappealable determination that the patent was not infringed; (2) HMR dismissed the patent infringement case; or (3) there was a final and unappealable deter-

---

[3] The payments were scheduled to end on the earliest of: (1) a final and unappealable order or judgment in the patent infringement case; (2) if HMR notified Andrx that it intended to enter into a license agreement with a third party, the earlier of: (a) the expiration date of the required notice period or (b) the date Andrx effected its first commercial sale of the Andrx product; or (3) if Andrx exercised its option to acquire a license from HMR, the date the license agreement became effective.

[4] HMR and Andrx stipulated that, for the purposes of the Agreement, Andrx would have realized $100 million per year in profits from the sale of its generic product after receiving FDA approval.

mination that did not determine the issues of the patent's validity, enforcement, or infringement, and HMR failed to refile its patent infringement action.[5] HMR also agreed that it would not seek preliminary injunctive relief in the ongoing patent infringement litigation.[6]

On July 8, 1998, the statutory thirty-month waiting period expired. On July 9, 1998, the FDA issued its final approval of Andrx's ANDA. Pursuant to the Agreement, HMR began making quarterly payments of $10 million to Andrx, and Andrx did not bring its generic product to market.

On September 11, 1998, Andrx, in a supplement to its previously filed ANDA, sought approval for a reformulated generic version of Cardizem CD. Andrx informed HMR that it had reformulated its product; it also urged HMR to reconsider its infringement claims. On February 3, 1999, Andrx certified to HMR that its reformulated product did not infringe the '584 patent.

On June 9, 1999, the FDA approved Andrx's reformulated product. That same day, HMR and Andrx entered into a stipulation settling the patent infringement case and terminating the Agreement. At the time of settlement, HMR paid Andrx a final sum of $50.7 million, bringing its total payments to $89.83 million. On June

---

[5] HMR had to notify Andrx within thirty days of such a determination that it continued to believe that Andrx's generic version of the drug infringed its patent and that it intended to refile its patent infringement action.

[6] HMR also agreed that it would give Andrx copies of changes it proposed to the FDA regarding Cardizem CD's package insert and immediate container label, that it would notify Andrx of any labeling changes pending before or approved by the FDA, and that it would grant Andrx an irrevocable option to acquire a nonexclusive license to all intellectual property HMR owned or controlled that Andrx might need to market its product in the United States.

23, 1999, Andrx began to market its product under the trademark Cartia XT, and its 180-day period of marketing exclusivity began to run. Since its release, Cartia XT has sold for a much lower price than Cardizem CD and has captured a substantial portion of the market.

C. Procedural History

The first complaint challenging the legality of the Agreement was filed in August 1998, shortly after the FDA issued its final approval for Andrx's generic version of Cardizem CD. That complaint, and the other complaints that were subsequently filed, have been consolidated by the Judicial Panel on Multidistrict Litigation, pursuant to 28 U.S.C. § 1407, for coordinated or consolidated pretrial proceedings in the Eastern District of Michigan.[7] JA 56-58.

For all of the plaintiffs, the foundation for their claims is the allegation that but for the Agreement, specifically the payment of $40 million per year, Andrx would have brought its generic product to market once it received FDA approval and at a lower price than the patented

---

[7] As described by the district court, the plaintiffs fall into three groups: (1) the "State Law Plaintiffs," indirect purchasers, and class representatives, from various states whose complaints, initially filed in state court and then removed to federal district court by defendants, allege violations of state antitrust and consumer protection statutes, JA 908-1011; (2) the "Sherman Act Class Plaintiffs," direct purchasers, and class representatives, whose complaint, filed in federal district court, alleges a violation of federal antitrust law, JA 139-159; and (3) the "Individual Sherman Act Plaintiffs," two groups of purchasers, not representatives of any class, whose complaints, filed in federal district court, allege violations of federal antitrust law, JA 860-881 (filed by The Kroger Co., Albertson's, Inc., The Stop and Shop Supermarket Co., and Eckerd Corp.); JA 887-896 (filed by CVS Meridian, Inc. and Rite Aid Corp.). *See* Dist. Ct. Op. I, at 625-27. Each group has filed a brief on appeal.

Cardizem CD sold by HMR. They further allege that the Agreement protected HMR from competition from both Andrx and other potential generic competitors because Andrx's delayed market entry postponed the start of its 180-day exclusivity period, which it had agreed not to relinquish or transfer. The Sherman Act Class Plaintiffs and the Individual Sherman Act Plaintiffs bring claims under the federal antitrust laws, specifically section 1 of the Sherman Act, 15 U.S.C. § 1; they seek treble damages under section 4 of the Clayton Act, 15 U.S.C. § 4. The State Law Class Plaintiffs bring claims under various state antitrust laws.[8]

The defendants, HMR and Andrx, filed various motions to dismiss, all of which were denied. *See* Dist. Ct. Op. I, at 624. Of relevance to the present appeal, the defendants argued that all of the plaintiffs had failed to allege and could not allege an "antitrust injury" cognizable under section 1 of the Sherman Act or under the respective state antitrust statutes. *Id.* at 645. The district court concluded that the plaintiffs had adequately alleged "antitrust injury." *Id.* at 645-58. In reaching its conclusion, the district court first considered whether the plaintiffs' allegations satisfied the test articulated by the Supreme Court in *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). In *Brunswick*, the Supreme Court defined "antitrust injury" as "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." 429 U.S. at 489. The district court explained its conclusion that the plaintiffs satisfied this test as follows:

---

[8] Of the State Law Plaintiffs, the plaintiffs from seven states (California, Michigan, Minnesota, New York, North Carolina, Tennessee, and Wisconsin) and the District of Columbia claim violations of state antitrust law. Dist. Ct. Op. I, at 625 n.3.

> As to the first prong of the antitrust injury test, the Supreme Court has observed that "[t]he Sherman Act was enacted to assure our customers the benefits of price competition, and our prior cases have emphasized the central interest in protecting the economic freedom of participants in the relevant market." *Associated General*, 459 U.S. at 538. Plaintiffs are customers, not competitors of Defendants, and the injury claimed consists of higher prices paid for drugs as a result of the contractually mandated absence of competition between HMRI and Andrx. As to the second, or causal connection prong of the antitrust injury test, Plaintiffs have alleged that the HMRI/Andrx Agreement decreased generic competition, and that the decreased competition bargained for in the HMRI/Andrx Agreement caused their injuries. Thus, Plaintiffs' injuries coincide precisely with the rationale for finding a violation of the antitrust laws in the first place. Since the very purpose of antitrust law is to ensure that the benefits of competition flow to purchasers of goods affected by the violation, "buyers have usually been preferred plaintiffs in private antitrust litigation," and a purchaser's standing "to recover for an overcharge paid directly to an illegal cartel or monopoly is seldom doubted." 2 P. Areeda & H. Hovemkamp, supra, ¶ 370[,] at 253. Plaintiffs have sufficiently pled facts that show they satisfy the "antitrust injury" test set forth in *Brunswick*.

Dist. Ct. Op. I, at 650-51. The district court then considered whether the Sixth Circuit's decisions in *Axis, S.p.A. v. Micafil*, 870 F.2d 1105 (6th Cir. 1989), *Hodges v. WSM, Inc.*, 26 F.3d 36 (6th Cir. 1994), and *Valley Products Co. v. Landmark*, 128 F.3d 398 (6th Cir. 1997) required a different conclusion, Dist. Ct. Op. I, at 651-

57, particularly the statement in *Hodges* that "because plaintiffs did not allege, nor could they that the illegal antitrust conduct was a necessary predicate to their injury *or* that defendants could exclude plaintiffs only by engaging in the antitrust violation, it was appropriate to dismiss the case." 26 F.3d at 39 (emphasis added). After closely examining the facts and holdings of those cases, it rejected the defendants' contention that the Sixth Circuit's "necessary predicate" test meant that an antitrust complaint should be dismissed "simply because the defendant can conjure up a set of facts, contradicting those alleged in the plaintiff's complaint, but supporting an alternative possible cause for Plaintiffs' injuries that would not offend the antitrust laws." Dist. Ct. Op. I, at 651. It explained further:

> While the Sixth Circuit language found in the last paragraph of *Hodges* and repeated in *Valley Products* appears to broadly apply to the facts presented here, careful examination of these decisions reveals otherwise. The quoted language goes well beyond the antitrust injury test announced in *Brunswick*, goes well beyond what the Sixth Circuit actually did in each of these cases, goes further than the underlying facts allow, and is mutually inconsistent with the material cause standard that is to be applied in antitrust cases.

Id. at 652. Accordingly, the district court denied the defendants' motions to dismiss for failure to allege antitrust injury.

The plaintiffs then moved for partial summary judgment on the issue of whether the Agreement was a *per se* illegal restraint of trade. The district court concluded that the Agreement, specifically the fact that HMR paid Andrx $10 million per quarter not to enter the market

with its generic version of Cardizem CD, was a naked, horizontal restraint of trade and, as such, *per se* illegal. Dist. Ct. Op. II, at 705-06.

Pursuant to 28 U.S.C. § 1292(b), the district court certified for interlocutory appeal the two questions quoted above.[9]

II. DISCUSSION

As we believe that our answer to the second question sheds light on our consideration of the first, we address first whether the Agreement was a *per se* illegal restraint of trade before considering whether the plaintiffs adequately alleged antitrust injury.

A. *Per Se* Illegal Restraint of Trade

We review *de novo* the district court's ruling on summary judgment that the Agreement was a *per se* illegal restraint of trade. *Holloway v. Brush*, 220 F.3d 767, 772 (6th Cir. 2000). Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c).

---

[9] Since oral argument before this Court, the defendants have reached a settlement with the Sherman Act Class Plaintiffs. A settlement with the State Law Plaintiffs and the State Attorneys' General is subject for a final approval hearing before the District Court in October 2003. The Sherman Act Individual Plaintiffs have settled with HMR (now Aventis Pharmaceuticals), but have not settled with Andrx. The defendants have represented to the Court that these settlements have not mooted the certified issues presented by this appeal. *See* Letter to U.S. Court of Appeals for the Sixth Circuit, filed Feb. 20, 2003.

1. Relevant Antitrust Law

Section 1 of the Sherman Act[10] provides that "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal . . . ." 15 U.S.C. § 1. Read "literally," section 1 "prohibits *every* agreement in restraint of trade." *Arizona v. Maricopa Cty. Medical Soc.*, 457 U.S. 332, 342 (1982). However, the Supreme Court has long recognized that Congress intended to outlaw only "unreasonable" restraints. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); *Maricopa Cty.*, 457 U.S. at 342-43 (citing *United States v. Joint Traffic Ass'n*, 171 U.S. 505 (1898)). Most restraints are evaluated using a "rule of reason." *State Oil*, 522 U.S. at 10. Under this approach, the "finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Id.* (citing *Maricopa Cty.*, 457 U.S. at 343 & n.13).

Other restraints, however, "are deemed unlawful *per se*" because they "have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit." *Id.* (citing *Northern Pacific Ry. Co. v. United States*, 356 U.S. 1, 5 (1958)). "*Per se* treatment is appropriate '[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.' " *Id.* (quoting *Maricopa Cty.*, 457 U.S. at 344); *see also*

---

[10] It is undisputed that the state antitrust statutes at issue either follow federal Sherman Act precedent or find federal case law persuasive. *See* State Law Pls. Br. at 41-44.

Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1, 19-20 (1979) (a *per se* rule is applied when "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output."). The *per se* approach thus applies a "conclusive presumption" of illegality to certain types of agreements, *Maricopa Cty.*, 457 U.S. at 344; where it applies, no consideration is given to the intent behind the restraint, to any claimed pro-competitive justifications, or to the restraint's actual effect on competition.[11] *National College Athletic Ass'n ("NCAA") v. Board of Regents*, 468 U.S. 85, 100 (1984). As explained by the Supreme Court, "[t]he probability that anticompetitive consequences will result from a practice and the severity of those consequences must be balanced against its procompetitive consequences. Cases that do not fit the generalization may arise, but a *per se* rule reflects the judgment that such cases are not sufficiently common or important to justify the time and expense necessary to identify them." *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 n.6 (1977).

The Supreme Court has identified certain types of restraints as subject to the *per se* rule. The classic examples are naked, horizontal restraints pertaining to prices or territories. *See, e.g., NCAA*, 468 U.S. at 100 ("Hori-

---

[11] The risk that the application of a *per se* rule will lead to the condemnation of an agreement that a rule of reason analysis would permit has been recognized and tolerated as a necessary cost of this approach. *See, e.g., Maricopa Cty.*, 457 U.S. at 344 ("As in every rule of general application, the match between the presumed and the actual is imperfect. For the sake of business certainty and litigation efficiency, we have tolerated the invalidation of some agreements that a fullblown inquiry might have proved to be reasonable."); *United States v. Topco Associates, Inc.*, 405 U.S. 596, 609 (1972) ("Whether or not we would decide this case the same way under the rule of reason used by the District Court is irrelevant to the issue before us.").

zontal price fixing and output limitation are ordinarily condemned as a matter of law under an 'illegal *per se*' approach because the probability that these practices are anticompetitive is so high."); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984) ("Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused."); *United States v. Topco Assocs.*, 405 U.S. 596, 608 (1972) ("One of the classic examples of a *per se* violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition. Such concerted action is usually termed a 'horizontal' restraint, in contradistinction to combinations of persons at different levels of the market structure, *e.g.*, manufacturers and distributors, which are termed 'vertical' restraints. This Court has reiterated time and time again that horizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition. Such limitations are *per se* violations of the Sherman Act." (internal citations omitted)); *Northern Pacific Ry.*, 356 U.S. at 5 ("Among the practices which the courts have heretofore deemed to be unlawful in and of themselves are price fixing, division of markets, group boycotts, and tying arrangements." (internal citations omitted)).

2. Application

In answering the question whether the Agreement here was *per se* illegal, the following facts are undisputed and dispositive. The Agreement guaranteed to HMR that its only potential competitor at that time, Andrx, would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it

had obtained FDA approval, protecting HMR's exclusive access to the market for Cardizem CD throughout the United States until the occurrence of one of the end dates contemplated by the Agreement. (In fact, Andrx and HMR terminated the Agreement and the payments in June 1999, before any of the specified end dates occurred.) In the interim, however, from July 1998 through June 1999, Andrx kept its generic product off the market and HMR paid Andrx $89.83 million. By delaying Andrx's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer.[12] There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.

None of the defendants' attempts to avoid *per se* treatment is persuasive. As explained in greater detail in the

---

[12] As the district court for the Eastern District of New York recently observed, in distinguishing the district court's opinion in the present case (*Cardizem II*),

> By agreeing both not to end the underlying patent dispute and not to market a generic drug product in the relevant domestic market, Andrx . . . effectively precluded or seriously delayed both the [patent] court decision and the commercial marketing trigger of the 180-day exclusivity period. As a result, any future [generic] filers were delayed in coming to market . . . .

In re Ciprofloxacin Hydrochloride Antitrust Litigation, MDL No. 1383, 2003 WL 21146562, at *46 (E.D.N.Y. May 20, 2003); *see also In re Tamoxifen Citrate Antitrust Litigation*, MDL No. 1408, 2003 WL 21196817, at *9 (E.D.N.Y. May 13, 2003).

district court's opinion, *see* Dist. Ct. Op. II, at 700-705, the Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation. As the plaintiffs point out, it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness[13] in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market. Individual Sherman Act Plaintiffs Br. at 26-30. Nor does the fact that this is a "novel" area of law preclude *per se* treatment, *see Maricopa Cty.*, 457 U.S. at 349. To the contrary, the Supreme Court has held that " '[w]hatever may be its peculiar problems and characteristics, the Sherman Act, so far as price-fixing agreements are concerned, establishes one uniform rule applicable to all industries alike.' " *Id.* at 349 (quoting *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 222 (1940)). We see no reason not to apply that rule here, especially when the record does not support the defendants' claim that the district court made "errors" in its analysis.[14] Finally, the

---

[13] As the court in *In re Ciprofloxacin* observed,

> [w]hen the Cardizem [district] court condemned the HMR/Andrx Agreement, it emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation, ... Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.

2003 WL 21146562, at *46.

[14] For example, the defendants charge that the district court erred in concluding that in the absence of the Agreement, Andrx *would* have marketed its generic product before the end of the patent litigation (once it had received FDA approval). However, the district court never held that Andrx *would* have launched the original formulation of its generic while the patent suit was pending, only that

defendants' claims that the Agreement lacked anticompetitive effects and had procompetitive benefits are simply irrelevant. *See, e.g., Maricopa Cty.*, 457 U.S. at 351. To reiterate, the virtue/vice of the *per se* rule is that it allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or procompetitive justifications in a particular case. As the Supreme Court explained in *Maricopa County*:

> The respondents' principal argument is that the *per se* rule is inapplicable because their agreements are alleged to have procompetitive justifications. The argument indicates a misunderstanding of the *per se* concept. The anticompetitive potential inherent in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered for some. Those claims of enhanced competition are so unlikely to prove significant in any particular case that we adhere to the rule of law that is justified in its general application.

457 U.S. at 351. Thus, the law is clear that once it is decided that a restraint is subject to *per se* analysis, the claimed lack of any actual anticompetitive effects or

---

it *could* have. The defendants also contend that the district court erred in assuming that Andrx could have marketed its *reformulated* generic, which only received FDA approval in June 1999, before it did, but the district court made no such assumption. Finally, the defendants argue that the district court erred in reaching the conclusion that Andrx and HMRI were horizontal competitors. They maintain that it would be inconsistent with Hatch-Waxman scheme to allow a court to treat a generic manufacturer who is seeking FDA approval and has been charged with patent infringement and the patent holder as horizontal competitors. Hatch-Waxman notwithstanding, the defendants are potential rivals in the market for Cardizem CD; an agreement between them is thus an agreement between horizontal competitors.

presence of procompetitive effects is irrelevant. Of course, our holding here does not resolve the issues of causation and damages, both of which will have to be proved before the plaintiffs can succeed on their claim for treble damages under the Clayton Act.

B. Antitrust Injury

We now consider whether the district court properly denied the defendants' motion to dismiss the complaint for failure to allege an "antitrust injury."[15] A district court's denial of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) is subject to *de novo* review. *Ziegler v. IBP Hog Market, Inc.*, 249 F.3d 509, 511-12 (6th Cir. 2001). In deciding a motion to dismiss, we, like the district court, "must construe the complaint in the light most favorable to the plaintiff, accept all of the complaint's factual allegations as true, and determine whether the plaintiff undoubtedly can prove no set of facts in support of his claim that would entitle him to relief." *Id.* at 512. "When an allegation is capable of more than one inference, it must be construed in the plaintiff's favor." *Helwig v. Vencor*, Inc., 251 F.3d 540, 553 (6th Cir. 2001) (internal citations omitted), *cert. dismissed*, 536 U.S. 935 (2002).

---

[15] Our conclusion that the Agreement was a *per se* illegal restraint of trade does not obviate the need to decide whether the plaintiffs adequately alleged antitrust injury. *See Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 341-42 (1990) ("The *per se* rule is a method of determining whether § 1 of the Sherman Act has been violated, but it does not indicate whether a private plaintiff has suffered antitrust injury and thus whether he may recover damages under § 4 of the Clayton Act.").

1. Relevant Antitrust Law

A private antitrust plaintiff, in addition to having to show injury-in-fact and proximate cause, must allege, and eventually prove, "antitrust injury." *Brunswick*, 429 U.S. at 489. "Antitrust injury" is (1) "injury of the type the antitrust laws were intended to prevent" and (2) injury "that flows from that which makes defendants' acts unlawful." *Id.* As explained by the Supreme Court in *Brunswick*, the antitrust injury doctrine is designed to ensure that "the injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Id.* The Supreme Court has further explained the requirement as "ensur[ing] that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place," and, more specifically, it "ensures that a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior." *Atlantic Richfield Co. v. USA Petroleum Co.* 495 U.S. 328, 342-343 (1990).

2. Plaintiffs' Allegations

In the present case, the plaintiffs' critical allegations include the following: (1) Andrx had developed and was ready to market a generic version of Cardizem CD; (2) Andrx had certified to the FDA that its generic product did not infringe any of the patents associated with Cardizem CD; (3) the patent infringement litigation was a "sham"[16]; (4) prior to entering into the Agreement,

---

[16] The State Law Plaintiffs allege that the '584 patent "represented no substantive change or improvement to Cardizem CD but rather was prosecuted and listed solely to give HMR a basis for initiating sham patent infringement litigation to delay and exclude Andrx's generic Cardizem CD from the Cardizem CD market for at least 30 months." JA 948, ¶ 101. They further allege that Andrx's

Andrx had represented to the federal district court presiding over the patent infringement litigation that it intended to market and sell its generic version of Cardizem CD as soon as it received final FDA approval; (5) the Agreement entered into by Andrx and HMR provided, among other things, that once the FDA approved Andrx's ANDA, HMR would commence making quarterly payments of $10 million in exchange for Andrx not bringing its generic product to market; (6) Andrx did not enter the market upon receiving FDA approval on July 9, 1998; (7) pursuant to the Agreement, HMR ultimately paid Andrx $89.83 million; (8) "but for" the Agreement and the payment, Andrx would have begun to market its generic version of Cardizem CD on or shortly after July 9, 1998; (9) the Agreement effectively eliminated generic competition in the market for Cardizem CD from July 1998 through July 1999, when the Agreement was terminated; and (10) due to the lack of a competitive market, the plaintiffs were deprived of the option of purchasing a generic lower-priced drug and paid more than they otherwise would have for Cardizem CD. JA 908-1011 (State Law Pls. Compl.); JA 139-159 (Sherman Act Class Pls. Compl.); JA 848-859, 860-881, 887-896 (Individual Sherman Act Pls. Compls.); *see also* Dist. Ct. Op. I, at 647.

---

specified dissolution profile, submitted to the FDA after the patent infringement litigation was filed, was "clearly distinct" from the '584 patent, JA 949, ¶ 103, and that HMR continued its pursuit of the patent infringement litigation "despite the absence of any reasonable belief that their claim would be held to be valid upon adjudication," *id.* ¶ 104. Finally, they allege that HMR's "goal and intention in pursuing [the patent infringement litigation] was solely to indefinitely delay and prevent the entry of Andrx's product into the marketplace and invoke the automatic 30-month administrative delay in the FDA approval process." *Id.*; *see also* JA 154, ¶ 53 (amended complaint of Sherman Act Class Plaintiffs alleging that "patent litigation" was "sham[ ]")).

3. Application of *Brunswick*

The plaintiffs' allegations fall easily within the two critical *Brunswick* categories. It is clear, and not disputed on appeal, that the plaintiffs have alleged the "type of injury" the antitrust laws were meant to prevent. The plaintiffs are consumers of the patented drug Cardizem CD, who allege that they were deprived of a less expensive generic product, forcing them to purchase the higher-priced brand name product, because of a *per se* illegal horizontal market restraint. Preventing that kind of injury was undoubtedly a *raison d'etre* of the Sherman Act when it was enacted in 1890. *See Associated Gen. Contractors v. California State Council*, 459 U.S. 519, 538 (1983).

There remains the issue of whether the alleged injury "flows" from that "which makes defendants' acts unlawful," i.e., its anticompetitive effects. The facts of *Brunswick* shed light on the meaning and purpose of this requirement. In *Brunswick*, a bowling alley owner claimed that another competitor's takeover of two failing bowling alleys was an illegal merger. The plaintiff alleged that it was injured by the merger because if the other bowling alleys had simply gone out of business, it would have increased its sales in the bowling alley market. What would have made the acquisition unlawful for antitrust purposes, however, was the risk that increased concentration in the bowling alley market would reduce future competition and cause prices to rise. The plaintiff's injury, on the other hand, flowed from the more immediate competition-enhancing effects of the merger; not its future potential to reduce competition. Accordingly, there was no antitrust injury because the plaintiff's injury did not "flow" from the anticompetitive effects of the alleged antitrust violation.

In the present case, the facts are much more straightforward. As explained above, the alleged antitrust violation, HMR's agreement to pay Andrx $40 million per year not to bring its generic product to market and compete with Cardizem CD, is a naked, horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers. Unlike in *Brunswick*, here there is no question that the alleged injury—paying higher prices for a product due to a lack of competition in the market—is the type of injury that can, and the plaintiffs have alleged did, flow from the anticompetitive effects of the Agreement (a horizontal market allocation agreement). Under these circumstances, dismissal would be appropriate only if the plaintiffs' allegations, taken as true and construed in their favor, somehow precluded the possibility that their injury flowed from the anticompetitive effects of the Agreement and payment. No such conclusion can be reached in this case. To the contrary, the complaint clearly alleges that but for the Agreement, specifically the payment of $40 million per year, the plaintiffs would not have suffered their injury; there is nothing in the complaint that belies this allegation or justifies this Court not accepting it as true. The defendants' argument to the contrary, that Andrx would not have entered the market even if there had been no Agreement and payment because of its fear of damages in the patent infringement litigation, creates a disputed issue of fact, not appropriately resolved on a motion to dismiss. Indeed, a trier of fact may well find that the $89 million payment renders incredible the defendants' claim that Andrx would have refrained from marketing simply because of its fear of infringement damages.

4. "Necessary Predicate" Test

We turn now to the defendants' contention, and the reason for this certified appeal, that the Sixth Circuit's "necessary predicate" test requires more than *Brunswick* and leads to a different conclusion.[17] The defendants' argument arises out of a statement made in this Court's decision in *Hodges*. In that case, after having decided to affirm the district court's dismissal for failure to allege

---

[17] It is noteworthy that the district court has responsibility for these cases by assignment of the Judicial Panel on Multidistrict Litigation, and we address this certified question in aid of the district court. This consolidated proceeding includes cases that were originally filed in various state and federal courts, raising state and federal antitrust claims. The state cases were first removed to federal district court and then transferred to the Eastern District of Michigan. In considering the issue of antitrust injury, the district court applied the same analysis, including the application of Sixth Circuit precedent, to all of the antitrust claims. *Id.* at 645-58. As no party has taken issue with this approach, either before the district court or on appeal, we have followed the same path. We note, however, that although it is clear and undisputed that the state antitrust laws at issue all "either follow federal Sherman Act precedent or find federal case law persuasive," Dist. Ct. Op. II, at 692 & n.6 (citing state cases); *see also* State Law Pls. Br. at 41-15, and that in a federal multidistrict litigation there is a preference for applying the law of the transferee district, *see In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050 (8th Cir. 1996); *Menowitz v. Brown*, 991 F.2d 36 (2d Cir. 1993), it is not clear that precedent "unique" to a particular circuit and arguably divergent from the predominant interpretation of a federal law, such as the Sixth Circuit's "necessary predicate" gloss on the antitrust injury doctrine, should be applied to state antitrust laws or federal antitrust claims that originated in other circuits, *see In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171 (2d Cir. 1987), *aff'd*, 490 U.S. 122 (1989) (law of transferor forum on federal question merits close consideration, but does not have *stare decisis* effect). As we agree with the district court that the plaintiffs have alleged antitrust injury as contemplated by the Sixth Circuit, this consideration is of academic interest only. Were the outcome otherwise, it might require further consideration.

antitrust injury, the Court stated: "[b]ecause plaintiffs did not allege, nor could they, that the illegal antitrust conduct was a necessary predicate to their injury *or* that defendants could exclude plaintiffs only by engaging in the antitrust violation, it was appropriate to dismiss the case pursuant to Federal Rule of Civil Procedure 12(b)(6)." *Hodges*, 26 F.3d at 39 (emphasis added).

The defendants contend that this statement means that in order to allege antitrust injury adequately, a plaintiff must allege that the only way the defendant *could* have caused the plaintiff's injury was by engaging in the antitrust violation. Defs. Br. at 32-33. In other words, if the defendant could have in theory caused the same injury without engaging in an antitrust violation, the plaintiff has not suffered an "antitrust injury," even if in fact it was the antitrust violation that caused the actual injury in a particular case. Applied to the present case, the defendants contend that the plaintiffs cannot allege an antitrust injury because Andrx *could* have unilaterally (and legally) decided not to market its generic version of Cardizem CD; they contend it is immaterial whether, in fact, it was the Agreement and the payment of $40 million per year that caused them to do so. *Id.*

We disagree.

First, simply looking at the actual language of the statement suggests that the defendants have conflated two ideas. What the court in *Hodges* said was that in order to survive a motion to dismiss for failure to allege antitrust injury, a plaintiff must allege *either*: (1) that the antitrust violation was "a necessary predicate" to their injury; *or* (2) that the defendants could injure plaintiffs only by engaging in the antitrust violation. 26 F.3d at 39. The defendants' interpretation conflates these options, effectively requiring plaintiffs to satisfy the second one even if they have already satisfied the first.

Second, nothing in the facts or holding of *Axis*, *Hodges*, or *Valley Products*, the cases relied upon by the defendants, supports their interpretation. Although it does not use the "necessary predicate" language, we consider first the Sixth Circuit's decision in *Axis*, the starting point for this line of antitrust injury cases.

In *Axis*, 870 F.2d 1105, the plaintiff was a foreign manufacturer of armature winding machines which sought to enter the United States market. After another foreign manufacturer purchased two American manufacturers, the plaintiff filed an antitrust suit against the purchaser claiming that the purchase was illegal because it reduced competition in the armature winding machine market. The plaintiff's alleged injury was its exclusion from the United States market. However, the plaintiff also alleged that it could not enter the market because it lacked access to indisputably valid and essential patents controlled by the defendant; the plaintiff did not challenge the legal right of the patent-holder to refuse to grant it a license. Nor did it or anyone else challenge the validity of the patents. We affirmed dismissal of the complaint because it failed to allege antitrust injury, noting that the "the anticompetitive act of purchasing [the American manufacturer] did not cause the plaintiff's alleged injury. The patents were an *impenetrable* barrier to the plaintiff's entry before [the defendant] purchased [the American manufacturer], and they remained as great a barrier afterwards." 870 F.2d at 1107 (emphasis added).

In *Hodges*, 26 F.3d 39, the plaintiff was an airport shuttle and tour bus operator who wanted to participate in the market for shuttle services from the Nashville airport to Opryland, an amusement park, hotel and convention center. It filed an antitrust suit against the companies that owned the Opryland site and operated the Grand Old Opry music radio program, as well as a sight-

seeing and tour company known as Grand Old Opry tours. The complaint alleged that those defendants had reached an illegal market division agreement with other shuttle and tour bus operators that the competitors would refrain from transporting passengers from the airport to the Opryland complex, leaving the airport shuttle market to the defendants themselves. In exchange, the defendants would hire vans and buses from their former competitors for Opryland's sightseeing tour business. The plaintiff's alleged injury was its exclusion from the airport to Opryland shuttle market. The plaintiff further alleged that the defendants policed their illegal agreement by refusing the plaintiff, and any other non-conspiring shuttle service companies, access to the Opryland property; the plaintiff did not challenge the defendants' lawful right to exclude it from their private property. The case was dismissed for failure to allege antitrust injury.

In *Valley Products*, 128 F.3d 398, the plaintiff was a manufacturer of logo-bearing hotel soaps and other hotel amenities which wanted to supply its products to franchisees of a certain hotel franchisor. The hotel franchisor authorized certain vendors to use its trademark on products, which the franchisees would then purchase. After the plaintiff's vendor agreement was terminated, it filed an antitrust suit against the hotel franchisor and its two remaining authorized vendors, the plaintiff's competitors, alleging that their arrangement was an attempt to impose an illegal tying arrangement on franchisees (by conditioning the franchise agreement on the purchase of logoed amenities from the two preferred vendors). There was no allegation that the vendors and the franchisor had agreed to exclude the plaintiff. The plaintiff's alleged injury was its exclusion from the logoed amenity market for the defendant franchisor's franchisees. The case was

dismissed for failure to allege antitrust injury. On appeal, we observed that the Sixth Circuit "has been reasonably aggressive in using the antitrust injury doctrine to bar recovery where the asserted injury, although linked to an alleged violation of the antitrust laws, flows directly from conduct that is not itself an antitrust violation." *Valley Products*, 128 F.3d at 403.

As the above discussion of *Axis*, *Hodges* and *Valley Products* demonstrates, the facts and holdings of those cases provide no support for the defendants' proposed interpretation of the "necessary predicate" language in *Hodges*. In none of these cases was a complaint dismissed for failure to allege antitrust injury based on a defendant's claim that it *could* have caused the same injury without committing the alleged violation. Rather, the complaints were dismissed for failure to allege antitrust injury because each of the defendants had taken an action that it was lawfully entitled to take, independent of the alleged antitrust violation, which was the actual, indisputable, and sole cause of the plaintiff's injury. In *Axis*, the antitrust violation was not the "necessary predicate" because the plaintiff's alleged injury—its exclusion from competing in the armature winding machine market—admittedly flowed not from the anticompetitive effects of the allegedly illegal purchase, but from its lack of access to "impenetrable" patents. 870 F.2d at 1107. In *Hodges*, the antitrust violation was not the "necessary predicate" because the plaintiff's alleged injury—its exclusion from competing in the shuttle services from the airport to the Opryland site owned by defendants—actually flowed not from the anticompetitive effects of an allegedly unlawful market division agreement, but from the defendants' "lawful refusal to grant plaintiffs access to their private property." 26 F.3d at 39. In *Valley Products*, the antitrust violation was not

the "necessary predicate" because the plaintiff's alleged injury—its exclusion from competing in the franchisor's logoed amenity market—actually flowed, not from the anticompetitive effects of an allegedly unlawful tying arrangement, but from the defendant's lawful termination of a vendor agreement.[18] Thus, in reality, we have only dismissed a case for failure to allege that an antitrust violation is the "necessary predicate" for the plaintiff's injury where it has been apparent from the face of the complaint that actual and unequivocally legal action by the defendant would have caused plaintiff's injury, even if there had been no antitrust violation.

Application to this case of the "necessary predicate" test, as we have applied it in the cases which are the subject of the certified question, demonstrates that the district court correctly refused to dismiss these complaints for failure to allege antitrust injury. In essence, as exposed by the *per se* analysis above, *see supra* Part II.A., the complaints allege a plain vanilla horizontal agreement to restrain trade in the form of a multi-million dollar cash payment in consideration for forbearance by Andrx from selling on the market a product that it was ready and able to sell at a price lower than that charged by HMR for the patented product. There is nothing on the face of the complaint that suggests, much less establishes as a matter of law, that there was any physical or "impenetrable" legal impediment to Andrx's production and sale of its FDA-approved generic product. Indeed, some plaintiffs allege that HMR's patent infringement suit against Andrx was a "sham." JA 948, ¶ 101; JA 949,

---

[18] This court's decision in *Watkins & Son Pet Supplies v. Iams Co.*, 254 F.3d 607 (6th Cir. 2001), similarly found no antitrust injury where the plaintiff's alleged injury—its exclusion from the market—flowed from the termination of its distributorship, not from the defendants' allegedly illegal distribution restraints.

¶¶ 103-04; JA 154, ¶ 53. Nor can the defendants identify a lawful right that they had and exercised and that indisputably caused plaintiffs' injury. Thus, the complaint may be fairly construed as alleging that the *per se* illegal Agreement with its $89 million payment, not HMR"s disputed 45%-18 patent, constituted the "necessary predicate" for Andrx's decision to keep its FDA-approved 55%-18 generic product off the market and HMR free from *any* generic product competition. The fact that Andrx could have unilaterally, and legally, decided not to bring its generic product to a manifestly profitable market has no relevance in assessing whether the plaintiffs adequately alleged that the antitrust violation was the necessary predicate for their injury.[19]

What remains is the defendants' contention that Andrx would have stayed out of the market even absent the Agreement and the payment of $40 million per year because Andrx feared incurring damages in the patent infringement litigation. Proof of allegations on the face of this complaint and reasonable inferences therefrom, however, could persuade a trier of fact that had HMR been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished. Under the aegis of the complaint and inferences, a fact trier could also find that even if it is a "prudent" industry practice for a generic manufacturer to stay out of the market until

---

[19] In addition, the defendants' position, if adopted, risks undermining a basic premise of antitrust law that, as the district court observed, in many instances, an otherwise legal action—*e.g.* setting a price—becomes illegal if it is pursuant to an agreement with a competitor. Under the defendants' view, such an action would never cause antitrust injury because a defendant *could* have unilaterally and legally set the same price.

the resolution of patent infringement litigation, Defs. Br. at 33, in this case, the patent infringement suit was a "paper tiger" incapable of deterring the generic producer from entering the market as soon as the FDA approved its product—as it had formally advised the patent court. If proved to be true, it would almost necessarily follow that the plaintiffs' injury flowed from the Agreement and payment of $40 million per year. At this stage of the litigation, we must leave this dispute for the trier of fact to evaluate.

III. CONCLUSION

For the foregoing reasons, we answer both of the district court's certified questions as follows: it properly resolved the questions that it put to us in the course of denying defendants' motions to dismiss and granting the plaintiffs' motions for summary judgment that the defendants had committed a per se violation of the antitrust laws.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Master File No. 99-md-1278
MDL No. 1278

Honorable Nancy G. Edmunds

IN RE: CARDIZEM CD ANTITRUST LITIGATION.

THIS DOCUMENT RELATES TO:
ALL ACTIONS,

ORDER NO. 13

MEMORANDUM OPINION AND ORDER GRANTING PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

State Law Plaintiffs and Sherman Act Plaintiffs[1] are before the Court on motions, brought pursuant to Fed. R.

---

[1] The Sherman Act Plaintiffs include all Plaintiffs in the Sherman Act class cases and the Sherman Act individual cases consolidated in this Court, Case Nos. 99-73870, 99-73259, 99-73735, and 99-75036.

Civ. Pro. 56(a), for partial summary judgment. Plaintiffs' motions raise a single issue, whether Defendants' September 24, 1997 Agreement ("HMRI/Andrx Agreement") constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and under the various state antitrust laws at issue here. This Court answers this question in the affirmative. It concludes that the HMRI/Andrx Agreement is an agreement between horizontal competitors that allocates the entire United States market for Cardizem CD and its bioequivalents to Defendant HMRI, and thus constitutes a restraint of trade that has long been held illegal *per se* under established Supreme Court precedent. *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990); *United States v. Topco Associates, Inc.*, 405 U.S. 596 (1972); *United States v. Cooperative Theatres of Ohio, Inc.*, 845 F.2d 1367 (6th Cir. 1988). Accordingly, Plaintiffs' motions for partial summary judgment are **GRANTED**.

I. Facts

A. Relevant Statutory and Regulatory Framework

The manufacture and distribution of pharmaceutical drugs are regulated by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. (1994). Congress passed the "Hatch-Waxman Amendments" to the Act in 1984 after concluding that the Act's "cumbersome drug approval process delayed the entry of relatively inexpensive generic drugs into the market place." *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D. D.C. 2000). The Hatch-Waxman Amendments, 21 U.S.C § 355 (1994), embody Congress' intent "to make available more low cost generic drugs" and its attempt "to balance

two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Id.* (internal quotes and citations omitted).

"[T]he Hatch-Waxman Amendments established new guidelines for the approval of generic drugs. Generic drug makers were permitted to file an Abbreviated New Drug Application ("ANDA") which incorporated data that the 'pioneer' manufacturer had already submitted to the FDA regarding the pioneer drug's safety and efficacy. In order to obtain FDA approval, the ANDA must demonstrate, among other things, that the generic drug is 'bioequivalent' to the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(iv). As protection for pioneer drug makers, the applicant is also required to certify in one of four ways that the generic drug will not infringe on any patent which claims the pioneer drug. *See id.* at § 355(j)(2)(A)(vii)." *Mylan Pharm.*, 81 F. Supp. 2d at 32.

Applicable here is the fourth type of certification. Paragraph IV certification "permits the applicant to allege that the patent for the pioneer drug is either invalid or will not be infringed by the marketing of the generic drug. See id. at § 355(j)(2)(A)(vii)(IV)." *Mylan Pharm.*, 81 F. Supp. 2d at 32. As the District Court for the District of Columbia recently observed, "[a] generic drug manufacturer's filing of a so-called 'Paragraph IV' certification has important legal ramifications. It automatically creates a cause of action for patent infringement. Upon receiving notice of a Paragraph IV certification's filing, the patent holder or pioneer manufacturer has 45 days within which to file suit against the generic manufacturer. *See id.* at § 355(j)(5)(B)(iii). If such an action is brought, the FDA cannot approve the

generic manufacturer's ANDA for 30 months. *See id.* However, if the court hearing the infringement action rules before the expiration of the 30-month period that the patent at issue is 'invalid or not infringed,' then 'the approval shall be made effective on the date of the court decision[.]' *Id.* at § 355(j)(5)(B)(iii)(I)." *Mylan Pharm.*, 81 F. Supp. 2d at 32-33.

To encourage competitors to bring cheaper generic drugs to market, and acknowledging that they will likely incur "potentially substantial litigation costs associated with challenging pioneer drug makers' patents, the Hatch-Waxman Amendments provide an added incentive for generic drug producers to file Paragraph IV certifications. The first generic manufacturer to file an ANDA containing a Paragraph IV certification with respect to a specific patent is awarded a 180-day period of exclusive marketing rights for a generic version of the drug claimed by that patent. In other words, no other ANDA for the same generic drug product will be approved during those 180 days." *Id.* at 33.

Section 355(j)(5)(B)(iv) provides that:

> If the [ANDA] contains a certification described in [Paragraph IV] and is for a drug for which a previous application has been submitted under this subsection [containing a Paragraph IV] certification, the application shall be made effective not earlier than one hundred and eighty days after—
>
> (I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or
>
> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is

> the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

Id. (quoting 21 U.S.C. § 355(j)(5)(B)(iv)). Accordingly, the 180-day period of exclusivity "can be triggered in one of two ways-either (1) when the generic producer begins commercial marketing of its drug (the 'commercial marketing trigger'), or (2) when there is a court decision finding the pioneer drug maker's patent invalid or not infringed (the 'court-decision trigger')." *Mylan Pharm.*, 81 F. Supp. 2d at 33 (footnote omitted).

B. Andrx's ANDA, the HMRI/Andrx Patent Suit, ANDA Supplements, and the September 1997 HMRI/Andrx Agreement

Prior to August 1995, Defendant Andrx had been developing its own generic version of Cardizem CD, and provided samples of its proposed generic substitute for Cardizem CD to the Hoechst Defendants so they could perform their own tests to confirm that there was no infringement of the patents claiming Cardizem CD and thus avoid litigation.

On September 22, 1995, Andrx filed its Abbreviated New Drug Application ("ANDA") No. 74-752 with the United States Food & Drug Administration ("FDA") seeking approval to manufacture and sell a generic form of Cardizem CD, a once-daily, controlled release dosage of the chemical compound diltiazem hydrochloride, manufactured and sold by Defendant HMRI.

On November 28, 1995, two months after Andrx filed its ANDA, the U.S. Patent and Trademark Office issued U.S. Patent No. 5,470,584 ("the '584 patent") to Carderm which then licensed it to HMRI. The '584 patent claims a delayed release diltiazem formulation with an

in-vitro dissolution profile where from 0-45% of total diltiazem is released after 18 hours and not less than 45% of total diltiazem is released after 24 hours.

On December 31, 1995, Andrx made a Paragraph IV Certification with regard to all unexpired patents listed in the FDA's Orange Book[2] allegedly claiming Cardizem CD and certified to HMRI that the product reflected in its ANDA did not infringe the patents owned or controlled by HMRI or its affiliates, including the '584 patent.

On January 31, 1996, HMRI and Carderm filed a patent infringement suit against Andrx in the District Court for the Southern District of Florida ("HMRI/Andrx patent case"). The filing of the suit triggered the 30-month Hatch-Waxman waiting period, which expired on or before July 8, 1998. Thus, Andrx's ANDA could not be finally approved and it could not begin commercial marketing of its generic version of Cardizem CD until the 30-month waiting period expired or the court hearing the infringement action ruled that the patent at issue was invalid or not infringed, whichever first occurred. *See Mylan Pharm.*, 81 F. Supp. 2d at 32-33.

On April 4, 1996, Andrx filed an amendment to its ANDA No. 74-752, amending the dissolution profile to provide that not less than 55% of the total diltiazem was to be released after 18 hours. HMRI was notified of this change but continued to prosecute its infringement claims against Andrx.

On September 15, 1997, the FDA issued its tentative approval of Andrx's ANDA, which was an indication

---

[2] A list of patents believed to be covered by a pioneer drug product or its use must be submitted to the FDA, and the patents are listed in a publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."

that the ANDA would be approved as soon as it was legally eligible; i.e., on July 8, 1998, the date the 30 month Hatch-Waxman waiting period was due to expire, or earlier if the court presiding over the HMRI/Andrx patent infringement action ruled that the '584 patent was invalid or not infringed.

Less than ten days later, on September 24, 1997, HMRI and Andrx entered into the HMRI/Andrx Agreement. It is this Agreement that Plaintiffs assert constitutes a per se violation of § 1 of the Sherman Act.

By July 9, 1998, the FDA had granted final approval of Andrx's ANDA for a generic version of Cardizem CD, the 30 month Hatch-Waxman waiting period had expired, and Andrx was no longer restricted under the Hatch-Waxman Amendments from immediately marketing and selling its generic drug.[3] Under the terms of the HMRI/Andrx Agreement, however, Andrx had agreed not to enter the market with its generic version of Cardizem CD, and on July 9, 1998, HMRI's obligation to begin making quarterly payments of $10 million to Andrx was triggered.

Two months later, on September 11, 1998, Andrx filed a prior approval supplement to its ANDA No. 74-752 seeking to once again change the dissolution profile of its generic drug. Specifically, Andrx sought permission to make the following change: "in addition to adding a small amount of a new ingredient to the SR2 bead coating, the Prior Approval Supplement submitted on September 11, 1998 requests permission to change the current 0.1 N HC1 dissolution specification for the SR2

---

[3] The FDA's approval of Andrx's ANDA meant that FDA had found that the Andrx drug was "bioequivalent" to Cardizem CD and this in turn would make it possible, if not required, for pharmacists to fill prescriptions for Cardizem CD with Andrx's generic version of that drug. *See* Decl. of HMRI expert, A. Bennett, at ¶6.

bead *from 'not less than 55% of the total diltiazem released after 18 hours' to 'not less than 65% of the total diltiazem released after 18 hours'* ". *See* HMRI Appendix, Ex. 7 at 11 (emphasis added).

On October 7, 1998, Andrx informed HMRI that it had filed a prior approval supplement to its ANDA and urged HMRI to reconsider its infringement claims. *See* HMRI Appendix, Ex. 8, 6/9/99 Stipulation of settlement in HMRI/Andrx patent infringement action, ¶ 10; Bennett Decl. at ¶ 18; Bennett Decl., Ex. A at ¶ 15.

In January 1999, there was a flurry of activity. On January 8, 1999, HMRI wrote to Andrx suggesting that Andrx was required to file a new Para. IV certification, and on January 15, 1999, HMRI's counsel raised the same concerns with the FDA. *See* Bennett Decl. at ¶ 20. Then, on January 20 and 22, 1999, Andrx sent samples of its generic product with the new formulation to HMRI. *See* Bennett Decl., Ex. A at ¶¶ 19, 20.

On February 3, 1999, Andrx certified to HMRI that the reformulated product did not infringe the '584 patent. *See*. HMRI Appendix, June 9, 1999 Settlement Stip., Ex. 8 at ¶ 7. In its Second Supplemental Patent Certification ("Para. IV Certification"), Andrx asserted that the '584 patent would not be infringed by "the making, using or selling of the Andrx CARTIA XT because neither the Andrx CARTIA XT product nor any component of the Andrx CARTIA XT product exhibit an in-vitro dissolution profile that is the same as or equivalent to the in-vitro dissolution profile set forth in claims 1-9 of U.S. 5,470,584." HMRI Appendix, Ex. 7, Second Supplemental Patent Certification at 10.[4]

---

[4] Andrx further explained that "[i]n addition to adding a small amount of a new ingredient to the SR2 bead coating, the Prior Approval Supplement submitted on September 11, 1998 requests permission to change the current 0.1 N HC1 dissolution specification for

Andrx further asserted that "the claims of U.S. 5,470,584 cannot be read to include the SR2 bead in Andrx's CARTIA XT product because of *statements made by Eli Shefter regarding the scope of the claims* of U.S. 5,470,584 in paragraph 13 of the Second Declaration Eli Shefter submitted in the lawsuit, *Hoechst Marion Roussel, et al. v. Andrx Pharmaceuticals, Inc.*, Civil Action No. 96-06121 CIV-Roettger (S.D. Fla.)." *Id.* at 13 (emphasis added). Andrx explained that it was providing "[a] more detailed discussion of this point" in a separate addendum to its Second Supplemental Notice, and also explained that the addendum was being provided "only to Carderm Capital L.P. and Hoechst Marion Roussel, Inc. because Carderm Capital L.P. is the owner of U.S. 5,470,584 and the NDA for Cardizem CD and because the addendum contains confidential information Andrx obtained from Carderm Capital L.P. and Hoechst Marion Roussel, Inc. in *Hoechst Marion Roussel et al. v. Andrx Pharmaceuticals, Inc.*, Civil Action No. 96-06121 CIV-Roettger (S.D. Fla.) that is subject to the terms of a Stipulated Protective Order." *Id.* at 13-14.

In its Confidential Addendum to its Second Supplemental Patent Certification, Andrx reiterated that "all SR2 or slower release beads in the Andrx CARTIA XT product will release not less than 65% of the total

---

the SR2 bead from 'not less than 55% of the total diltiazem released after 18 hours' to 'not less than 65% of the total diltiazem released after 18 hours'. As clearly shown by the dissolution profiles attached hereto as Exhibit B, and more importantly the new 0.1 N HC1 dissolution specification of 'not less than 65% of the total diltiazem being released after 18 hours', neither the Andrx CARTIA XT product nor the individual SR1 beads and SR2 beads employed in the Andrx CARTIA XT product exhibit a dissolution profile that is within the three (3) specific dissolution ranges required by claims 1-9 of U.S. 5,470,584 and therefore cannot infringe any claim of U.S. 5,470,584." *Id.* at 11.

amount of diltiazem after 18 hours when tested according to the conditions recited in claim 1 of the '584 patent." HMRI Appendix, Ex. 7, Confidential Addendum to Andrx's Second Supplemental Patent Certification at 1. Andrx further explained that: "[t]his dissolution specification at the 18 hour point is more than 40% greater or 20 percentage points higher than the 45% maximum recited in claim 1 of the '584 patent." *Id.* Accordingly, Andrx asserted, "based upon arguments presented by HMR and HMR's expert, Dr. Shefter, in responding to Andrx's motions for summary judgment for non-infringement and invalidity in the *HMR v. Andrx* case, HMR cannot, in good faith, assert that SR2 beads which release 'not less than 65% of the total diltiazem after 18 hours' literally infringe claim 1 of the '584 patent" or infringe claim 1 under the doctrine of equivalents." *Id.* at 2-3. Specifically, Andrx asserted that: (1) in a 1/23/97 Eli Shefter Decl. at ¶ 38, Shefter had opined that he would consider the range of variability of the 18 hour dissolution measurement for these beads to be closer to 20% than 10%; (2) in a 1/23/97 Decl. at ¶ 42, Shefter had opined that "results ranging from 63 to 70% are not within the range of variability attributable to measurement limitations of the dissolution test"; (3) in a 3/7/97 Eli Shefter Decl., he had opined that "the error at 18 hours should be about + or - 10% or measured values of about 35% to 55% drug released"; (4) therefore "the scope of claim 1 of the '584 patent is limited to a maximum amount of 55% of diltiazem released after 18 hours"; and (5) accordingly, "SR2 beads that will release not less than 65% of diltiazem after 18 hours are clearly outside the scope of claim 1 of the '584 patent as interpreted by HMR." Id. at 2. Andrx further contended that "if HMR were to assert that claim 1 of the '584 patent includes SR2 beads that release not less than 65% of the

total diltiazem after 18 hours under the doctrine of equivalents, that construction [would] require the claims of the '584 patent to include the prior art" and HMR's own expert "Dr. James W. McGinity has confirmed that United States Patent Nos. 5,002,776 and 4,894,240 disclose a delayed release diltiazem bead that releases 65% of the total diltiazem after 18 hours." *Id.* at 3.

On June 9, 1999, the FDA's approval of Andrx's prior approval supplement to its ANDA No. 74-752 became effective. *See* Bennett Decl. at ¶ 23. Also on June 9, 1999, over four months after Andrx filed its Second Supplemental Para. IV Patent Certification, Andrx and HMRI entered into a stipulation settling the HMRI/Andrx patent litigation, and terminated the HMRI/Andrx Agreement.

The stipulation settling the HMRI/Andrx patent infringement action provided that: (1) HMRI continues to assert that the formulation of the Andrx product identified in the complaint did and continues to infringe the '584 patent; and Andrx continues to assert that it does not or that such patent is invalid (Stip. at ¶ 5); (2) on September 11, 1998, Andrx filed a supplement to ANDA 74-752 with the FDA which provided a reformulation of the product that Andrx intends to sell; i.e., a modification in formulation and the dissolution specification for one of the intermediates for the product—diltiazem hydrochloride extended-release SR2 pellets; (3) on February 3, 1999, Andrx certified to HMRI that the reformulated product reflected in the supplement does not infringe HMRI's patents; (4) Andrx intends to market the reformulated product following FDA approval and, unless it obtains a license from HMRI prior to that time, shall not market in the U.S. its earlier version of said product; (4) the reformulated product has SR2 pellets with average dissolution at 18 hours of not less than

68%; (5) HMRI stipulates that it will not prosecute a claim alleging patent infringement as to the reformulated product or seek to enjoin Andrx from marketing the reformulated product provided that the dissolution values are met or exceeded; (6) approval by the FDA of the reformulated product shall constitute final judgment under the September 24, 1997 HMRI/Andrx Agreement; and (7) any obligations arising under Paragraph 7(B) of the September 24, 1997 HMRI/Andrx Agreement (regarding license fees to be paid if Andrx had exercised its option and obtained a license from HMRI) shall be deemed fully satisfied without any further or other payments by either party to the other. *See* HMRI Appendix, Ex. 8, 6/9/99 Stipulation ("Settlement Agreement") in HMRI/Andrx patent case.

On June 23, 1999, Andrx began to commercially market Cartia XT and Andrx's 180-day period of exclusivity began to run. Since the time it has been marketed, Andrx's generic drug, Cartia XT, has been sold at a lower price than HMRI's Cardizem CD.

On June 24, 1999, the court entered an order dismissing the HMRI/Andrx patent infringement action.

By June 1999, when the HMRI/Andrx Agreement was terminated, HMRI had paid Andrx more than $89.83 million under the terms of that Agreement.

C. Consolidated Suits Against Defendants

These cases involve claims that the Defendants violated section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and various state antitrust and unfair competition statutes. Plaintiffs allege the following contract, combination or conspiracy in restraint of trade: Defendant Andrx developed a generic drug which is the bioequivalent to the Hoechst Defendants' prescription drug Cardizem CD. Andrx's generic drug was approved by

the FDA for sale and could have entered the U.S. market on or about July 9, 1998. Andrx, however, did not enter the market at that time because it had agreed with its horizontal competitor, HMRI, that it would delay the entry of its generic version of Cardizem CD in exchange for, *inter alia*, non-refundable payments of $40 million per year from HMRI. Plaintiffs allege that this agreement is embodied in a September 24, 1997 document executed by Defendants HMRI and Andrx (the "HMRI/Andrx Agreement").

The HMRI/Andrx Agreement was executed nine days after the FDA preliminarily approved Defendant Andrx's generic drug as the first AB-rated generic bioequivalent for Cardizem CD. It is alleged that, under the terms of the Agreement, Defendant Andrx agreed not to market its generic drug when it received FDA approval, and agreed not to transfer, assign, or relinquish its right to a 180-day exclusivity period that Andrx would enjoy once it finally did begin to market its generic version of Cardizem CD, and Defendant HMRI agreed to pay Andrx $10 million quarterly, beginning on the date the Andrx product received FDA approval, and for as long as Andrx complied with the terms of the HMRI/Andrx Agreement. Thus, it is alleged that the HMRI/Andrx Agreement not only protected HMRI from competition from Andrx, but it also protected HMRI from competition from other generic competitors because Andrx's delayed entry would postpone the start of its 180-day exclusivity period, and Andrx's agreement not to give up or transfer its right to that 180-day period of exclusivity would preclude other generic competitors from entering the market until that 180-day exclusivity period expired.

D. FTC Complaint Against Defendants

On March 16, 2000, the Federal Trade Commission filed a complaint against HMRI, Carderm Capital L.P., and Andrx Corp. alleging that (1) the HMRI/Andrx Agreement constitutes an unreasonable restraint of trade in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45;[5] (2) HMRI had the specific intent to preserve its monopoly in the relevant market and narrower markets contained therein, and its actions—including proposing, negotiating and entering into the HMRI/Andrx Agreement and its proposal of a similar agreement with Biovail—created a dangerous probability that it would accomplish its monopolistic objectives, in violation of Section 5 of the FTC Act, as amended; (3) Defendants acted with the specific intent that HMRI monopolize the relevant market and engaged in overt acts described in the FTC complaint in furtherance of a conspiracy to monopolize the relevant markets, in violation of Section 5 of the FTC Act, as amended; and (4) the acts and practices described in the FTC complaint are anti-competitive in nature and tendency and constitute unfair methods of competition in violation of Section 5 of the FTC Act, as amended.

A hearing on the FTC complaint is set for November 14, 2000.

II. Summary Judgment Standard

Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving

---

[5] The Supreme Court has observed that "[t]he FTC Act's prohibition of unfair competition and deceptive acts or practices, 15 U.S.C. § 45(a)(1), overlaps the scope of § 1 of the Sherman Act, 15 U.S.C. § 1, aimed at prohibiting restraint of trade". *California Dental Ass'n v. Federal Trade Comm'n*, 526 U.S. 756, ___ n. 3, 119 S. Ct. 1604, 1609 n. 3 (1999).

party is entitled to judgment as a matter of law. Fed.R. Civ. P. 56(c). The central inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986). After adequate time for discovery and upon motion, Rule 56(c) mandates summary judgment against a party who fails to establish the existence of an element essential to that party's case and on which that party bears the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

The movant has an initial burden of showing "the absence of a genuine issue of material fact." *Celotex*, 477 U.S. 317, 323. Once the movant meets this burden, the non-movant must come forward with specific facts showing that there is a genuine issue for trial. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

III. Analysis

The Sherman Act Class Plaintiffs and the Individual Sherman Act Plaintiffs argue that Defendants committed a *per se* violation of Section 1 of the Sherman Act when they entered into the September 24, 1997 HRMI/Andrx Agreement because it embodies an agreement to allocate the U.S. market for Cardizem CD and its bioequivalent AB-rated generics between HMRI and Andrx, who are horizontal competitors, and thus reduced competition, fixed the price of a widely prescribed heart medication, and unreasonably restrained trade. State Law Plaintiffs likewise assert that, because each of the jurisdictions implicated in their state law claims either follow federal Sherman Act precedent or find federal case law persuasive, the HMRI/Andrx Agreement of September 24,

1997 similarly constitutes a *per se* violation of the relevant state antitrust statutes.

The crux of Plaintiffs' argument is that well-established precedent and the undisputed facts show that: (1) agreements between actual or potential horizontal competitors to allocate markets are *per se* violations of the relevant antitrust laws; (2) the HMRI/Andrx Agreement is an agreement between actual or potential horizontal competitors to allocate markets, and thus the HMRI/Andrx Agreement constitutes a *per se* violation of the relevant antitrust laws; and (3) once a particular type of restraint has been placed in a *per se* category; i.e., horizontal market allocation agreement, it is conclusively presumed to be an unreasonable restraint of trade without an elaborate inquiry into purpose, power, or effects. *See, e.g., Topco*, 405 U.S. at 607; *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 221-22 (1940).

Defendants respond that the reasonableness of this alleged restraint of trade cannot be analyzed under the *per se* rule because the Agreement: (1) is not between actual or potential horizontal competitors; (2) does not allocate markets or fix prices and thus does not fall within the category of business practices analyzed under the *per se* rule; (3) is not a "naked" restraint of trade but rather was an agreement that was reasonably ancillary to pro-competitive activity; (4) is analogous to a patent settlement and thus should be analyzed under the rule of reason; and (5) is immunized from antitrust liability under the *Noerr-Pennington* doctrine. Defendant Andrx further responds that Plaintiffs' motions should be denied because determination of the issue presented will not materially simplify or expedite these cases. The Court addresses each of these arguments in turn, beginning with Andrx's argument that partial summary judgment on the issue presented is inappropriate.

A. Propriety of Partial Summary Judgment

Defendant Andrx argues that Plaintiffs' motions for partial summary judgment are improper because resolution of the issue presented will not streamline the litigation process, materially shorten discovery or trial, or conserve judicial resources. This Court disagrees. Plaintiffs clarify that they seek only a ruling that the HMRI/Andrx Agreement is a naked horizontal market allocation agreement and is thus a *per se* violation of the relevant antitrust laws, putting aside for the time being all issues of causation, injury and damages required for private recovery under section 4 of the Clayton Act, 15 U.S.C. § 15. Although Plaintiffs will still be required to prove causation, injury and damages, a decision that the Agreement is *per se* unreasonable will obviate the need for an "elaborate inquiry into the reasonableness of a challenged business practice" and the costs associated with such an inquiry. *See Arizona v. Maricopa County Medical Soc'y*, 457 U.S. 332, 343 (1982). Resolution of the issue presented here will greatly narrow the scope of discovery, will streamline the issues to be decided at trial, and will thus serve the interests of judicial economy. Other courts have similarly entertained motions for summary judgment on the issue whether a defendant's challenged activities were illegal *per se* under section 1 of the Sherman Act. *See Arizona v. Maricopa*; *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990); *New York ex rel. Spitzer v. Saint Francis Hosp.*, 94 F. Supp. 2d 399, 2000 WL 370531 (S.D. N.Y. April 10, 2000).

B. Per Se Analysis of the Challenged Restraint

The Court now considers whether the challenged restraint of trade is susceptible to analysis under the *per se* mode of analysis. The Court begins with a general

description of the essential elements of Plaintiffs' Sherman Act and state law antitrust claims and the *per se* mode of analysis. It then clarifies that the question as to which mode of analysis is to be applied presents a question of law for the Court and that the critical inquiry, regardless of the mode of analysis, is whether the challenged restraint restricts rather than enhances competition.

1. General Principles

a. Violations of Section 1 of the Sherman Act

"The essential elements of a violation of Section 1 of the Sherman Act are: 1) a contract, combination or conspiracy; 2) affecting interstate commerce; 3) which imposes an 'unreasonable' restraint on trade." *White and White, Inc. v. American Hosp. Supply Corp.*, 723 F.2d 495, 504 (6th Cir. 1983). The courts use two methods of analysis, the *per se* rule and the rule of reason, to determine "whether restraints of trade unreasonably restrict competition." *Cooperative Theatres*, 845 F.2d at 1370. "[T]he first employs a presumption that an agreement is an antitrust violation, thus invoking a per se illegality rule to classify the agreement; the second, called 'rule of reason' analysis, requires the factfinder to decide whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint of trade." *Betkerur v. Aultman Hosp. Ass'n,* 78 F.3d 1079, 1088 (6th Cir. 1996) (internal quotes and citations omitted).

b. State Law Antitrust Claims

It is not disputed that the state antitrust statutes at issue here either follow federal Sherman Act precedent or find federal case law persuasive. Accordingly, a decision that the HMRI/Andrx Agreement is illegal *per se*

under § 1 of the Sherman Act will likewise result in a similar decision under the relevant California, District of Columbia, Michigan, Minnesota, New York, North Carolina, Tennessee and Wisconsin antitrust statutes.[6]

---

[6] *See Marin County Bd. of Realtors, Inc. v. Palsson*, 16 Cal. 3d 920, 925, 130 Cal. Rptr. 1, 549 P.2d 833 (1976), *Truta v. Avis Rent a Car System, Inc.*, 193 Cal. App. 3d 802, 822, 238 Cal. Rptr. 806 (Cal. App. 1987) (observing that California's Cartwright Act "is patterned after the federal Sherman Anti-trust Act and decisions under the latter are applicable as an aid to a decision in interpreting the former"); D.C. Code Ann. § 28-4502 (D.C.'s counterpart to § 1 of the Sherman Act) and § 28-4515 (1998) (expressly stating the intent that the courts are to use federal precedent interpreting federal antitrust laws as a guide to interpretation of D.C.'s antitrust laws); Mich. Comp. Laws § 445.784 (1999) (expressly directing the courts to give "due deference to interpretations given by the federal courts to comparable antitrust statutes, including, without limitation, the doctrine of *per se* violations" in construing the Michigan Antitrust Reform Act); *State by Humphrey v. Alpine Air Prod., Inc.*, 490 N.W.2d 888, 894 (Minn. App. 1992) (observing that the "Minnesota court's have consistently held that Minnesota antitrust law is to be interpreted consistently with the federal courts' construction of federal antitrust law"), *aff'd*, 500 N.W.2d 788 (1993); *People v. Rattenni*, 179 A.D.2d 691, 692, 578 N.Y.S.2d 257 (N.Y. App. Div. 1992) (observing that "[a]lthough we do not move in lockstep with the Federal courts in our interpretation of antitrust law . . . the Donnelly Act . . . should generally be construed in light of Federal precedent" and further observing that "[i]t is well established that the horizontal customer allocation agreement would constitute a *per se* violation of the Sherman Act, the federal antitrust statute, and there is no reason for a different conclusion under the New York Statute"), *aff'd*, 81 N.Y.2d 166, 597 N.Y.S.2d 280, 613 N.E.2d 155 (1993); *DKH Corp. v. Rankin-Patterson Oil Co., Inc.*, 131 N.C. App. 126, 506 S.E.2d 256, 258 (N.C. App. 1998) (observing that the North Carolina courts will look to federal antitrust decisions for guidance in determining the scope and meaning of North Carolina's antitrust statute); *State ex rel. Leech v. Levi Strauss*, 1980 WL 4696 at *2 n. 2 (Tenn. Chancery Ct. 1980) (observing that "[a]uthorities which define the character of private damage suits under the federal anti-trust statutes, particularly the Sherman Act, are most persuasive"); Tenn. Code Ann. §§ 47-25-101 (1999) (providing

c. Per Se Analysis

The Supreme Court has observed that "certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anti-competitive that each is illegal *per se* without inquiry into the harm it has actually caused." *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984). *See also Arizona v. Maricopa County Medical Soc.*, 457 U.S. 332 (1982) (horizontal price-fixing arrangement); *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (per curium) (horizontal market allocation agreement); *Topco*, 405 U.S. at 608 (observing that "[o]ne of the classic examples of a violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition"); *Cooperative Theatres*, 845 F.2d 1367 (6th Cir. 1988) (horizontal agreements to allocate markets among competitors); *Blackburn v. Sweeney*, 53 F.3d 825 (7th Cir. 1995) (same). Accordingly, "[i]n those horizontal price-fixing [and market allocation] cases where the per se rule applies, the only inquiry is whether there was an agreement to restrain trade, since the unreasonableness of the restraint is conclusively presumed regardless of whether the rule of reason would lead to a different result." *Re/Max Int'l v. Realty One, Inc.*, 900 F. Supp. 132, 148 n. 8 (N.D. Ohio, 1995) (citing *Maricopa County Medical Soc'y*, 457 U.S.

---

that any "arrangements, contracts, [and] agreements . . . which tend to lessen . . . full and free competition" are unlawful); *State v. Waste Management of Wis., Inc.*, 81 Wis. 2d 555, 261 N.W.2d 147, 155 (1978) (observing that conspiracies in restraint of trade under the Sherman Act are likewise conspiracies in restraint of trade under the Wisconsin antitrust act); *Indep. Milk Producers Co-op v. Stoffel*, 102 Wis. 2d 1, 298 N.W.2d 102, 104-05 (Wis. Ct. App. 1980) (observing that "[c]onduct labeled as *per se* illegal includes price fixing, group boycotts, horizontal market allocation, resale price maintenance, and tying arrangements").

at 344), *aff'd*, 173 F.3d 995 (6th Cir. 1999), *petition for cert. filed*, 68 U.S.L.W. 3138 (Aug. 17, 1999) (No. 99-294).

As Professor Hovenkamp explains, "[c]ourts often say that a 'naked' horizontal restraint is illegal 'per se.' What this label means in practice is that (a) neither a relevant market nor an estimate of the defendants' market power must be established to prove that the restraint is unlawful; (b) harmful effects are presumed; and (c) the range of permissible defenses is severely limited." 11 H. Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 1910a at 252 (1998 ed.) (footnotes omitted). "[T]he justification for the per se rule rests on an implicit and rather loose 'cost-benefit' analysis concluding that for certain classes of restraints the added costs of applying a rule of reason are not justified by the resulting improvement in accuracy of outcome." *Id.* The rule "is based on the premise that particular restraints are unreasonable as a class. As a result, once the tribunal concludes that the restraint at issue is within the class, further inquiry into the merits of that particular restraint is unwarranted." *Id.* at ¶ 1910b, p. 252 (emphasis in original).

The Sixth Circuit has similarly observed, "a court's choice between a per se rule and 'rule of reason' analysis is driven largely by analogy. A court should find a per se antitrust violation only when prior cases have established the anti-competitive effects of a sufficiently similar business practice," *Betkerur*, 78 F.3d at 1089. Business practices condemned under the *per se* rule include horizontal agreements to allocate markets and to fix prices. *See Copperweld Corp.*, 467 U.S. at 768. The Sixth Circuit has further observed that, " 'horizontal' restraints—that is, agreements among competitors at the same level of the market structure—are particularly sus-

pect because they typically serve no purpose other than to stifle competition," *Betkerur*, 78 F.3d at 1092.

d. Question of Law for the Court

The question presented here; i.e., whether to apply a *per se* or rule of reason mode of analysis in determining the reasonableness of the challenged restraint of trade, is a question of law for the Court. *See In re American Honda Motor Co., Inc. Dealership Relations Litig.*, 941 F. Supp. 528, 562 (D. Md. 1996). "While applying any one of antitrust's modes of analysis might involve many fact questions, the selection of a mode is entirely a question of law," 11 H. Hovenkamp, *supra*, ¶ 1909b at 251 (citing *Maricopa County Medical Society*, 457 U.S. at 337 n. 3). As Professor Hovenkamp observes, "the entire premise of the per se rule is that *judicial* experience with a certain class of restraints justifies more expedited treatment." Hovenkamp, *supra* ¶ 1909b at 251 (citing *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents*, 468 U.S. 85, 100-101 (1984)). Accordingly, the testimony of Defendant HMRI's expert, Dr. Roger Blair, opining that the HMRI/Andrx Agreement should be analyzed under the rule of reason rather than the *per se* rule, inappropriately renders an opinion on a question of law that rests solely within the province of the Court and thus is not considered here.

e. Critical Inquiry—Does the Challenged Restraint Enhance Competition

Despite the identification of different modes of analysis for determining the reasonableness of a challenged restraint of trade, the Supreme Court has observed that the ultimate goal is to answer the critical question whether the challenged restraint enhances or impairs

competition. Regardless of whether the "unreasonableness" finding " 'is the product of a presumption [under a *per se* analysis] or actual market analysis [under a rule of reason analysis], the essential inquiry remains the same—whether or not the challenged restraint enhances competition.' " *California Dental Ass'n v. Federal Trade Comm'n*, 526 U.S. 756, ___, 119 S. Ct. 1604, 1617 (1999) (quoting *Nat'l Collegiate*, 468 U.S. at 104). Thus, "[e]very antitrust suit should begin by identifying the ways in which a challenged restraint might possibly impair competition," 7 P. Areeda, *Antitrust Law* ¶ 1503a at 372 (1986 ed.). This applies to *per se* cases as well. "Although a per se rule is seemingly satisfied merely by showing, say, 'price fixing,' specifying the competitive evil helps reassure us that the challenged conduct actually falls in that category." Id. at 372, n. 1. "Identifying the type of possible harm to competition is the first essential step." 7 P. Areeda, *supra*, ¶ 1503 at 374.

Accordingly, this Court will first construe the terms of HMRI/Andrx Agreement and identify whether the challenged restraints in that Agreement might, on their face, impair or enhance competition. The Court will then address Defendants' arguments that the HMRI/Andrx Agreement is: (1) not between actual or potential horizontal competitors; (2) not a market allocation or price fixing agreement; (3) not a "naked" restraint of trade but rather is an agreement reasonably ancillary to a pro-competitive activity; (4) analogous to a patent settlement agreement and thus should be analyzed under the rule of reason mode of analysis; and (5) immunized from antitrust liability under the *Noerr-Pennington* doctrine.

2. Construction of the HMRI/Andrx Agreement —Identifying Whether the Challenged Restraints Enhance or Inhibit Competition

a. General Principles

The HMRI/Andrx Agreement is to be interpreted in accordance with the general principles of contract law, and, as provided in ¶ 11 of that Agreement, "all the terms and provisions" "shall be construed under the laws of the State of Florida." Under Florida law, "the interpretation of a written contract is a matter of law to be determined by the court." *DEC Elec., Inc. v. Raphael Constr. Corp.*, 558 So. 2d 427, 428 (Fla. S. Ct. 1990). Accordingly, this Court does not consider the testimony of Defendant HMRI's experts, A. Bennett and R. Blair, or that of Defendant Andrx's Vice President/General Counsel, Scott Lodin, that construe the terms of the HMRI/Andrx Agreement or proffer testimony that is contrary to this Court's construction of the Agreement. *See* A. Bennett Decl. at ¶¶ 11, 12; R. Blair Decl. at ¶¶ 5, 8, 17; and S. Lodin Decl. at ¶¶ 8, 15, 17-20, 22-23, 25.

"Contract interpretation principles under Florida law require [the Court] to look first at the words used on the face of the contract to determine whether that contract is ambiguous. It is well settled that the actual language used in the contract is the best evidence of the intent of the parties and, thus, the plain meaning of that language controls." *Rose v. M/V "Gulf Stream Falcon"*, 186 F.3d 1345, 1350 (11th Cir. 1999) (citations omitted). Furthermore, "under Florida law, . . . 'whereas' or other prefatory clauses are not binding" and "although, the 'whereas' clause may be evidence of parties' intent, [the Court] need not even look to the 'whereas' clause if the operative portion of the contract is unambiguous." *Id.* at 1350.

b. The HMRI/Andrx Agreement

To give the Court's construction of the HMRI/Andrx Agreement some context, the Court sets forth the following undisputed facts. On September 15, 1997, the FDA issued tentative approval of Andrx's ANDA, which was an indication that the ANDA would be approved as soon as it was legally eligible; i.e., on or about July 8, 1998, the date the 30-month Hatch-Waxman waiting period was due to expire. Less than ten days after the FDA's tentative approval, the Defendants entered into the HMRI/Andrx Agreement. The Agreement was entered into while the patent infringement action between HMRI and Andrx was pending. The Agreement, however, was not presented to, filed in, or approved by the court presiding over that patent infringement action.

On September 11, 1998, Andrx filed a prior approval supplement to its ANDA No. 74-752 seeking permission to add a small amount of a new ingredient to the SR2 bead coating and to change the dissolution specification for the SR2 bead from not less than 55% of total diltiazem being released after 18 hours to not less than 65% being released after 18 hours. On June 9, 1999, the FDA's approval of Andrx's prior approval supplement to its ANDA No. 74-752 became effective. Also on June 9, 1999, HMRI and Andrx filed a stipulation agreeing to settle the HMRI/Andrx patent case. Andrx did not commence marketing or selling its generic version of Cardizem CD until June 23, 1999, after the HMRI/Andrx Agreement was terminated and the HMRI/Andrx patent case was settled.

The Court now construes the terms of the HMRI/Andrx Agreement. The Agreement acknowledged that Andrx had formulated a bioequivalent or generic version of Cardizem CD and had filed an ANDA with the FDA seeking the right to sell the generic drug identified in its

ANDA. The Agreement identified Andrx's generic version of Cardizem CD as "the Andrx Product" and defined it as "the product Andrx intends to sell pursuant to the ANDA on file with the FDA *and as said ANDA may be amended consistent with this subparagraph.*" Agreement at ¶ 8(B)(iv) (emphasis added). Thus, the Andrx Product which was the subject of the HMRI/Andrx Agreement was that described in Andrx's ANDA No. 74-752 and that described in any amendment or modification to Andrx's ANDA No. 74-752 not requiring withdrawal of that ANDA or submission of a new ANDA. *Id.*

The Agreement also acknowledged that: (1) the Andrx Product was the subject of a pending patent infringement action brought by HMRI against Andrx; (2) HMRI had asserted its intent to seek an injunction barring Andrx from marketing, distributing or selling the Andrx Product prior to entry of a final and unappealable order or judgment in the HMRI/Andrx patent infringement case; (3) Andrx was aware of the financial risks it faced if HMRI sought and obtained injunctive relief or ultimately prevailed in its patent infringement action, as well as the risk of losing substantial revenues from the Andrx Product if it were to refrain from selling the Andrx Product until after a final and unappealable order or judgment was issued in its favor in the HMRI/Andrx patent case; and (4) although HMRI and Andrx intended to fully and vigorously litigate the infringement and validity issues in the pending HMRI/Andrx patent case, they also wished to reduce the risk of loss inherent in that litigation. *See* HMRI/Andrx Agreement at 1-2 ("Whereas" clauses).

Under the unambiguous terms of the HMRI/Andrx Agreement, Andrx agreed that it would not "commence the commercial sale" of its generic version of Cardizem

CD (which was the subject of its pending ANDA) "*or other bioequivalent or generic version of Cardizem CD*" in the United States either directly or indirectly until the earlier of: (1) entry of a final and unappealable order or judgment in the pending HMRI/Andrx patent infringement case; (2) Andrx obtained a license from HMRI after exercising its option under the terms of the HMRI/Andrx Agreement;[7] or (3) HMRI provided notice of the date that either HMRI or a third party licensee was authorized to make its first commercial sale of a bioequivalent or generic version of Cardizem CD. *See* HMRI/Andrx Agreement at ¶ 2(A) (emphasis added).

Andrx further agreed that, while the HMRI/Andrx patent infringement case was pending, it would "diligently prosecute" its ANDA and would "not relinquish or otherwise compromise any right accruing thereunder or pertaining thereto." *Id.* Andrx was allowed to modify or amend its ANDA as long as that did not require it to withdraw its existing ANDA. ¶ 8(B)(iv). The clear intent here was to protect the 180-day period of exclusivity awarded to Andrx under the Hatch-Waxman Amendments as the first-filed ANDA with a Paragraph IV certification.

Andrx also agreed to dismiss, without prejudice, its antitrust and unfair competition counterclaims filed against HMRI in the HMRI/Andrx patent case. As between HMRI and Andrx, the dismissal was deemed to be with prejudice on the effective date of a final and unappealable order or judgment in the HMRI/Andrx

---

[7] The Agreement provided three opportunities for Andrx to exercise its option to obtain a license, including an opportunity to exercise its option and obtain a license while the HMRI/Andrx suit remained pending; i.e., in January 2000 (18 months after FDA approval of the Andrx Product). *See* HMRI/Andrx Agreement ¶ 6(A)(ii).

patent case "provided that HMRI had fully complied with the terms" of the Agreement. *See* HMRI/Andrx Agreement at ¶ 2(C).

Accordingly, on its face, the HMRI/Andrx Agreement: (1) restrained Andrx from marketing its generic version of Cardizem CD in July 1998 when FDA approval was expected and obtained; (2) restrained Andrx from marketing other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending HMRI/Andrx patent case, including the reformulated generic drug described in its September 11, 1998 prior approval supplement to Andrx's ANDA No. 74-752; and (3) restrained Andrx from relinquishing or otherwise compromising its right to the 180-day period of exclusivity it obtained under the Hatch-Waxman Amendments.

HMRI agreed, under the unambiguous terms of the HMRI/Andrx Agreement, that it would not seek preliminary injunctive relief against Andrx, that it would provide Andrx with copies of changes it proposed to the FDA regarding its Cardizem CD package insert and immediate container label, and that it would notify Andrx of any labeling change approved by the FDA regarding Cardizem CD. *See* HMRI/Andrx Agreement at ¶ 2(A), 2(B).

HMRI also agreed that it would make interim payments to Andrx in the amount of $40 million per year, payable quarterly, and beginning on the date Andrx's generic version of Cardizem CD received FDA approval (July 8, 1998). *Id.* at ¶ (4)(A). These interim payments were to end on: (1) the date of a final and unappealable order or judgment in the HMRI/Andrx patent case;[8]

---

[8] The HMRI/Andrx Agreement provided that, in the event there was a final unappealable determination in the HMRI/Andrx patent case that did not determine the validity, enforceability or infringement of the '584 patent and HMRI notified Andrx in writing

(2) in the event HMRI notified Andrx that it intended to license its intellectual property for the purpose of selling a generic version of Cardizem CD to a third party or intended to use this property itself for the same purpose, then the interim payments were to end on the earlier of: a) the expiration date of the required notice period, or b) the date Andrx effected its first commercial sale of the Andrx Product; or (3) in the event Andrx exercised its option to acquire a license from HMRI, then interim payments were to end on the date the license agreement became effective. *See* HMRI/Andrx Agreement at ¶¶ 4(A)-(C).

The Agreement, despite calling the interim quarterly payments "nonrefundable," required repayment if, prior to the effective date of a final and unappealable order or judgment in the HMRI/Andrx patent case: (1) Andrx commenced the commercial sale of the Andrx Product in the United States, directly or indirectly (¶ 8(B)(i)); (2) Andrx commenced the commercial sale of other bioequivalent or generic versions of Cardizem CD in the United States, directly or indirectly (¶ 8(B)(i)); (3) Andrx failed to diligently prosecute or withdrew its ANDA for the Andrx Product or relinquished or otherwise compromised any right accruing under its ANDA (¶ 8(B)(i)); (4) Andrx transferred, sold, or assigned, without HMRI's express written consent, any option or

---

within 30 days that it continued to believe that the Andrx Product infringed the '584 patent and that it would refile its action and did so within the time frame set forth in ¶ 8(C), then this renewed action would continue the obligations and rights set forth in the Agreement as if no final, unappealable determination had been entered. *See* HMRI/Andrx Agreement at ¶ 8(C). Accordingly, these interim payments and Andrx's agreement not to begin commercial marketing of the Andrx Product or to compromise its right to the 180-day period of exclusivity could continue beyond the time a final and unappealable judgment or order took effect in the HMRI/Andrx patent case.

licensing rights issued pursuant to the HMRI/Andrx Agreement (¶ 8(B)(i)); or (5) Andrx stipulated in writing or in open court and on the record that the '584 patent was valid and that the Andrx Product infringed the '584 patent before there was a court determination on those issues (¶ 8(D)). Each of these events, also terminated the Agreement. *See* HMRI/Andrx Agreement at ¶¶ 8(B)(i), 8(D).

HMRI also agreed to pay Andrx $100 million per year,[9] less the amount of interim payments previously paid to Andrx under the terms of the Agreement, if: (1) Andrx obtained a final and unappealable order or judgment in the HMRI/Andrx patent case determining that the '584 patent was invalid or unenforceable or that the Andrx Product did not infringe the '584 patent, (¶ 3(B)); (2) HMRI dismissed the HMRI/Andrx patent infringement case prior to the effective date of a final and unappealable order in the HMRI/Andrx patent case (¶ 8(A)); or (3) there was a final and unappealable determination in the HMRI/Andrx patent case that did not determine the issues of the '584 patent's validity, enforcement or infringement and HMRI failed to notify Andrx, within 30 days of that determination, that it continued to believe that the Andrx Product infringed the '584 patent and that it would refile, and did refile, its patent infringement action (¶ 8(C)).

HMRI further agreed to grant Andrx an irrevocable option to acquire a non-exclusive license to all intellectual property HMRI owned or controlled that Andrx may need to market its generic version of Cardizem CD in the United States. *See* HMRI/Andrx Agreement at ¶ 5.

---

[9] HMRI and Andrx stipulated that, for the purposes of this Agreement, "the profits that Andrx would have realized from the sale of the Andrx Product would be $100 million per year after FDA approval." HMRI/Andrx Agreement at ¶ 3(A).

Andrx was prohibited from transferring, selling, or assigning, without HMRI's express written consent, its option to acquire a license from HMRI or any rights granted to Andrx if it did exercise that option and acquired a license. *Id.* at ¶ 8(B). Andrx had only three opportunities to exercise the option to acquire a license: (1) within 30 days from the effective date of a final and unappealable order or judgment in the HMRI/Andrx patent case (¶ 6(A)(i)); (2) in the event a final and unappealable order or judgment had not been entered, then beginning at the earlier of: a) 18 months after FDA approval (January 2000), or b) the effective date of FDA approval for a third party to make and market a bioequivalent or generic version of Cardizem CD (which, under the terms of the Hatch-Waxman Amendments, could not occur until 180 days after Andrx either began commercial marketing of its generic version of Cardizem CD or there was a court decision that the '584 patent was invalid or not infringed by Andrx's generic drug), and ending 30 days after the effective date of a final and unappealable order or judgment in the HMRI/Andrx patent case (¶ 6(A)(ii)); or (3) in the event that HMRI notified Andrx that HMRI or another third party would be using HMRI's intellectual property for the purpose of selling a generic version of Cardizem CD, Andrx could exercise its option at any time beginning on the date it received notice from HMRI and ending on the effective date of a final and unappealable order or judgment in the HMRI/Andrx patent case (¶ 6(A)(iii)).

In the event Andrx decided to exercise its option to acquire a license, the Agreement also provided for license fees and royalty payments. *See* HMRI/Andrx Agreement at ¶ 7. HMRI was required to refund the license fees and royalty payments if: (1) a final and unappealable order or judgment in the HMRI/Andrx

patent case determined that the '584 patent was invalid or unenforceable or was not infringed (¶ 7(B)(i)); or (2) HMRI dismissed the HMRI/Andrx patent infringement action prior to the effective date of a final and unappealable order or judgment (¶ 8(A)).

Both parties agreed that: (1) they would not ask the court presiding over the HMRI/Andrx patent case for an order increasing or decreasing the Hatch-Waxman 30-month waiting period (¶ 2(D)); (2) "except as otherwise required by law or as otherwise may be requested by the court" in the HMRI/Andrx patent case, the terms and existence of the Agreement would be kept confidential (¶ 9); and (3) the Agreement "and any drafts thereof or any documents or records pertaining thereto or information derived therefrom" would not be introduced into evidence in the HMRI/Andrx patent case "or any other litigation for any purpose." HMRI/Andrx Agreement at ¶ 9.

c. Restraints of Trade and Likely Effects on Competition

On its face, the Agreement: (1) restrained Andrx from marketing its generic version of Cardizem CD in July 1998 when FDA approval was expected and obtained; (2) restrained Andrx from marketing other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending HMRI/Andrx patent case, including the reformulated generic drug described in its September 11, 1998 prior approval supplement to its ANDA No. 74-752, and thus restrained Andrx from marketing non-infringing or potentially non-infringing versions of Cardizem CD; and (3) restrained Andrx from relinquishing or otherwise compromising its right to the 180-day period of exclusivity it obtained under the Hatch-Waxman Amendments. The HMRI/Andrx Agree-

ment thus inhibited rather than enhanced generic competition for Cardizem CD and allocated the entire United States market for Cardizem CD and its bioequivalents to HMRI during the life of that Agreement. By restricting generic competition, the Agreement also allowed HMRI to maintain or fix the price of Cardizem CD at non-competitive price levels.

The Agreement's terms as to the $10 million quarterly payments to Andrx, beginning in July 1998 when Andrx obtained FDA approval of its generic version of Cardizem CD, further restrained generic competition. First, they provided Andrx with an incentive to stay off the market beyond the time when it could have commenced marketing its generic drug (July 1998). They further restrained generic competition by providing Andrx with an incentive not to relinquish its right to the 180-day exclusivity period for marketing that it had obtained under the Hatch-Waxman Amendments from its status as the first generic manufacturer to file an ANDA with a Paragraph IV certification. Other generic drug manufacturers filing second and subsequent ANDAs for generic versions of Cardizem CD were required to wait until Andrx's 180-day exclusivity period expired before they could obtain FDA approval and enter the market. *See Mylan Pharm*, 81 F. Supp. 2d at 33.

This Court concludes that the September 24, 1997 HMRI/Andrx Agreement is unlawful on its face and is a *per se* violation of Section 1 of the Sherman Act. Contrary to Defendants' arguments, the HMRI/Andrx Agreement is an agreement between horizontal competitors to minimize generic competition and to allocate the entire United States market for Cardizem CD to HMRI during the life of the Agreement. *See Topco*, 405 U.S. at 608 (observing that "[o]ne of the classic examples of a per se violation of § 1 is an agreement between competitors at

the same level of the market structure to allocate territories in order to minimize competition"). *See also Palmer*, 111 S. Ct. at 403 (observing that previous competition in the market is not required, that the "defendants in *Topco* had never competed in the same market, but had simply agreed to allocate markets", and further observing that horizontal market allocation agreements "are anti-competitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other"); *Cooperative Theatres*, 845 F.2d at 1372 (observing that "a horizontal agreement to allocate customers between competing companies is a per se violation of Section 1 of the Sherman Act"); *Blackburn v. Sweeney*, 53 F.3d at 827 (observing that "[h]orizontal agreements to allocate markets among competitors are *per se* violations of the Sherman Act"). The Court is not persuaded by Defendants' argument that the HMRI/Andrx Agreement is an agreement that was reasonably ancillary to pro-competitive activity rather than a "naked" restraint of trade.

d. Defendants' Arguments Against Per Se Treatment

1. The HMRI/Andrx Agreement is a Horizontal Agreement

Defendants do not dispute that they perform at the same level of the market structure or that they are currently competitors in the U.S. market for Cardizem CD or its bioequivalents. Nonetheless, Defendants argue here, as they did in their motions to dismiss, that they cannot be considered horizontal competitors because they were neither competitors nor potential competitors during the life of their Agreement. Specifically, Defen-

dants argue that, during that time, they were never in direct competition and, furthermore, cannot be considered potential competitors because, until HMRI's patent claims were resolved, Andrx had no right to compete.[10] Defendants' arguments are without merit. First, it is not necessary that Defendants be actual competitors at the time of their Agreement. *See Palmer*, 111 S. Ct. at 403 (observing that, to prove a *per se* violation, a plaintiff need not show that the defendants had previously competed in the relevant market). Furthermore, Defendants' potential competitor arguments are built on the erroneous presumptions that Andrx's generic drug would infringe the '584 patent and that potential rivalry means the ability to compete free from the risk of patent liability.[11] *See Order* No. 12, Mem. Op. & Order at 117-122.

"An arrangement is said to be 'horizontal' when (1) its participants are *either* (a) actual rivals at the time the agreement is made or (b) potential rivals at the time the agreement is made; *and* (2) the agreement eliminates some avenue of rivalry among participants." 11 H. Hovenkamp, *supra*, ¶ 1901b at 185. Despite arguments to the contrary, HMRI and Andrx were potential rivals at the time the HMRI/Andrx Agreement was made, and the

---

[10] In support of this position, Defendant HMRI proffers the testimony of its expert, G. Methvin, opining that it was more likely than not that HMRI would have prevailed on its patent infringement claims, that the Court would have adopted the claim construction urged by Defendant HMRI, and that HMRI would have been entitled to a preliminary injunction in the HMRI/Andrx patent infringement case. The Court does not consider this testimony because it inappropriately renders an opinion on questions of law that rest solely within the province of the Court; i.e., claim construction and the grant or denial of injunctive relief.

[11] Defendants refer to this as competing "without the threat of economic ruin." *See* Andrx Br. at 27.

Agreement eliminated an avenue of rivalry; i.e., Andrx's entry in the market with a generic version of Cardizem CD. Testimony by Andrx's Vice President/General Counsel, Scott Lodin, that, at the time the Agreement was made, Andrx did not consider itself to be a competitor or potential competitor of HMRI is to no avail. *See* S. Lodin Aff'd at ¶ 15. Mr. Lodin's testimony is contrary to this Court's construction of the HMRI/Andrx Agreement; i.e., the plain language of that Agreement reflects that Andrx was considered a potential rival of HMRI in the U.S. market for Cardizem CD and its bioequivalents.[12]

---

[12] Mr. Lodin's testimony is also belied by: (1) his earlier testimony that Andrx's "primary goal was to begin selling our product as soon as we could prudently do so, in order to provide consumers with a genuine alternative to HMR's brand name drug and to demonstrate that Andrx was a serious participant in the generic pharmaceutical industry", *Id.* at ¶ 5; and (2) contemporaneous public statements in 1997 and 1998 by both HMRI and Andrx showing that they had no trouble recognizing that they were one another's competitors in the relevant market. *See* Jt. App., Tab 2 at 37, October 1997 Andrx Amendment No. 1 to S-1 filing (where, in SEC filings, Andrx represented to its shareholders that it had submitted ANDAs to the FDA covering, *inter alia*, bioequivalent versions of "Cardizem CD which is marketed by HMR . . . . In September 1997 [Andrx] received tentative FDA approval of its ANDA for the bioequivalent version of Cardizem/registered trademark/ CD. As a result of the HMR Litigation, the FDA may not grant final approval of Andrx's ANDA for Cardizem/registered trademark/CD until after either the HMR Litigation is resolved in Andrx's favor or July 3, 1998 (30 months after HMRI received Andrx's certification that its product does not infringe the patents listed for Cardizem/registered trademark/CD"). *See also* Jt. App., Tab 5 at 9, 1998 Hoechst AG 20-F filing (where HMRI also specifically warned its shareholders that generic competition for its products in general would "erode market share and sales revenues" and, in particular, generic sales of Cardizem CD "would have a material adverse effect on the operating profit of the Group" and further observed that "[a]lthough Cardizem

2. The HMRI/Andrx Agreement Allocates the U.S. Market for Cardizem CD

Andrx sought to compete with HMRI in the sale of Cardizem CD and its bioequivalents. This is evident from its ANDA No. 74-752, its Paragraph IV certification, and the subsequent HMRI/Andrx patent litigation. Within ten days of the FDA's tentative approval of Andrx's generic version of Cardizem CD, Defendants entered into the HMRI/Andrx Agreement. The unambiguous terms of the HMRI/Andrx Agreement allocate the entire U.S. market for Cardizem CD and its bioequivalents to HMRI while compensating Andrx, its potential competitor, $10 million dollars a quarter for not marketing its generic version of Cardizem CD and for not relinquishing or compromising its right to the 180-day period of marketing exclusivity it obtained under the Hatch-Waxman Amendments. This Agreement is a straight forward horizontal market allocation agreement and thus fits within the category of business practices which have long been held illegal *per se* under section 1 of the Sherman Act. *See Topco*; *Palmer*; *Cooperative Theatres*, 845 F.2d at 1372; *Blackburn v. Sweeney*, 53 F.3d at 827.

Defendants' causation arguments do not require a contrary conclusion. Whether Andrx's prior unilateral deci-

---

CD . . . is protected by formulation patents that prevent competition by others using the same formulation, a number of companies have filed for approval by the United States Food and Drug Administration ("FDA") of generically substitutable once-daily diltiazem formulations (at least one of which has been approved for marketing), which they assert do not infringe these patents. Should any of these products be marketed and not infringe HMR's patents, it likely would have a material adverse effect on Cardizem CD sales and could have a material adverse effect on the operating profit of the Group. Marketing of such a product could occur as early as 1999").

sion, as opposed to the HMRI/Andrx Agreement, caused it to stay off the market after it had obtained FDA approval and the 30-month Hatch-Waxman waiting period had expired is not at issue here.[13] The anti-competitive effects of HMRI's patent are likewise not at issue. Rather than Andrx's unilateral decisions, the conduct at issue here is Andrx's bilateral agreement with HMRI, its horizontal competitor, that unambiguously allocates the entire market for Cardizem CD and its bioequivalents to HMRI for as long as the Agreement remained in effect. As the Supreme Court observed in *Socony-Vacuum Oil*, 310 U.S. at 224, n. 9, it is well settled that "conspiracies under the Sherman Act are not dependent on any overt act other than the act of conspiring, (citation omitted). It is the 'contract, combination . . . or conspiracy, in restraint of trade or commerce' which § 1 of the Act strikes down, whether the concerted activity be wholly nascent or abortive on the one hand, or successful on the other."

---

[13] *See* S. Lodin Decl. at ¶¶ 8, 14-16, 19, 22 (where Andrx's Vice President/General Counsel testifies that, prior to the time Andrx entered into the HMRI/Andrx Agreement, Andrx had already decided that it would not enter the market until the HMRI/Andrx patent suit was resolved and had already decided that it would not abandon its pending ANDA). The Supreme Court, apparently ignoring a similar defense, held a horizontal market allocation agreement *per se* illegal under § 1 of the Sherman Act. In *Palmer*, the defendant who agreed to withdraw from the Georgia market submitted an affidavit in the district court similarly averring that it had unilaterally decided to withdraw from the Georgia market before it entered into the challenged agreement. *See Palmer v. BRG of Georgia, Inc.*, 874 F.2d 1417, 1418 (11th Cir. 1989), *rev'd*, 498 U.S. 46, 112 L. Ed. 2d 349, 111 S. Ct. 401 (1990). Without regard to the defendant's affidavit as to its unilateral decision, the Supreme Court examined the challenged agreement on its face and held that the horizontal market allocation agreement in *Palmer* was illegal *per se*. *See Palmer*, 111 S. Ct. at 403.

As Professor Hovenkamp has observed, "[h]orizontal agreements are antitrust's most 'suspect' classification" and "*as a class* deserve stricter scrutiny than" unilateral acts or vertical agreements because "they pose the most significant dangers of competitive harm." 11 H. Hovenkamp, *supra*, ¶ 1902a at 190-91 (emphasis in original). "The main threat of horizontal agreements is that they can enable participants to reduce the output of goods in some market, thus causing higher prices, inefficient substitutions, and the resultant losses to consumer welfare," *Id.* at 191. Unilateral acts, on the other hand, "always pose a lower threat than horizontal combinations. By definition, a unilateral act does not limit the activities of actual or potential rivals." *Id.*, ¶ 1902b at 193.

The decisions Defendants rely upon do not support a contrary result. In *United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 648-49 (9th Cir. 1981), Westinghouse had entered into technical assistance agreements with some companies granting them licenses to manufacture, use, and sell certain electrical products under Westinghouse's foreign patents. No licenses were granted under Westinghouse's U.S. or Canadian patents. Nothing in the agreements, however, forbid the licensees from manufacturing, using, or selling the products covered by the foreign licenses in the United States or Canada. *Id.* at 645.

At the bench trial, the Government argued, *inter alia*, that they had established the necessary causal link for their antitrust case against Westinghouse by presenting evidence showing that the licensees had sought Westinghouse's approval before they attempted to sell the products listed in the technical assistance agreements in the United States. The district court disagreed, finding that the Government had not met its burden of proof *on the issue of causation* because the licensees had argued

that "they did not act on the basis of an illegal agreement with Westinghouse but rather out of fear of infringing Westinghouse's patents." *Id.* at 648-49 (internal quotes and citations omitted). The Ninth Circuit affirmed the district court's dismissal based on the Government's failure to meet its burden on the issue of causation observing that:

> If fear of patent infringement was the reason [the licensee] sought Westinghouse approval before selling products covered by the Agreements in the United States, then it cannot be said that the resulting lack of competition was the "effect" of the Agreements rather than the effect of Westinghouse's patent. *The government bears the burden of showing causation. It must show that some combination or conspiracy between the parties "actually causes injury to competition," . . . in violation of the antitrust laws. The district court's conclusion that the government failed to show this causal link is amply supported by the record.* . . . The desire of [the licensee] to avoid infringing upon Westinghouse's many patents perhaps even as to products only arguably covered by Westinghouse's patents undoubtedly has an effect on competition, but this is an effect *which results from* the monopoly granted by the patent laws and does not establish an antitrust violation by the companies in this case.

Id. at 649 (citations omitted) (emphasis added).

As clarified in the quoted passage, the critical issue in *Westinghouse* was whether the Government had satisfied its burden of proof by showing the necessary causal link between the alleged antitrust violation and injury. That is not the issue presented here. Rather, Plaintiffs' motions require this Court to: (1) consider the

HMRI/Andrx Agreement and its likely anti-competitive effects; (2) determine whether the challenged Agreement is properly classified as a horizontal market allocation agreement that is susceptible to analysis under the *per se* rule; and if so, (3) apply the *per se* rule and conclude that the restraint of trade created by the Agreement is presumptively unreasonable and thus illegal *per se*.

Defendant HMRI's reliance on *Miller Insituform, Inc. v. Insituform of North America, Inc.*, 830 F.2d 606, 608 (6th Cir. 1987) is likewise misplaced. In *Miller Insituform*, the issue presented was whether an exclusive licensee violated section 2 of the Sherman Act when it terminated an agreement to sublicense a patent. The Sixth Circuit held there was no violation, reasoning that the exclusive licensee had a lawfully acquired patent and was merely exercising its right, granted under the license, to exclude others from using the patented process that was the subject of its exclusive license. Unlike the situation in *Miller Insituform*, there is no termination of a sublicensing agreement at issue here. Plaintiffs do not base their antitrust claims on HMRI's litigation efforts to maintain its monopoly power under the '584 patent. Rather, their antitrust claims challenge as anti-competitive HMRI's and Andrx's Agreement to have Andrx refrain from entering the market with its generic version of Cardizem CD beyond the time when it could have entered the market, to have Andrx refrain from relinquishing or compromising its pending ANDA (which had the practical effect of delaying entry of other generic versions of Cardizem CD into the market), and to have HMRI pay Andrx tens of millions of dollars as long as it complied with these restraints.

The decision in *Dunlop Co., Ltd. v. Kelsey-Hayes Co.*, 484 F.2d 407, 417-18 (6th Cir. 1973), also fails to advance HMRI's arguments. In *Dunlop Co.*, the court

similarly held that a patent holder, who had the power under its patent to preclude others from marketing its patented product without offending the antitrust laws, could also issue licenses as to its patented products that contained territorial restrictions without violating the antitrust laws. Unlike *Dunlop Co.*, there is no restricted license at issue here that allocates the territorial market for Cardizem C.D. Rather, there is an Agreement between HMRI and Andrx that allocated the entire U.S. market for Cardizem CD and its bioequivalents to HMRI for the life of that Agreement. As discussed more fully *infra*, the Agreement broadly restrains Andrx from marketing not only the allegedly infringing Andrx Product but also other bioequivalent or generic versions of Cardizem CD.

3. The HMRI/Andrx Agreement is Not An Agreement Reasonably Ancillary to Pro-Competitive Activity

As further support for their argument that *per se* analysis is inappropriate here, Defendant HMRI argues that the challenged restraints of trade embodied in the HMRI/Andrx Agreement are reasonably ancillary to the Agreement's central pro-competitive purposes and thus must be analyzed under the rule of reason. Andrx, on the other hand, argues that the Agreement "had no anti-competitive effects at all and in fact had demonstrable pro-competitive effects." Andrx Resp. Br. at 26. The Court disagrees with Defendants and is not persuaded that the broad restraints in the HMRI/Andrx Agreement are ancillary to the allegedly pro-competitive provisions Defendants rely upon to advance their position. The plain terms of the Agreement belie Defendants' argument that this Agreement is the product of a cooperative venture designed to enhance competition and facilitate

product output in the relevant market. *See Polk Bros., Inc. v. Forest City Enterprises, Inc.*, 776 F.2d 185 (7th Cir. 1985).

Defendants identify the following competition-enhancing qualities of the HMRI/Andrx Agreement: (1) it maintained the status quo, allowed HMRI and Andrx to manage their litigation risks, operated like a court-ordered preliminary injunction with a Fed. R. Civ. P. Rule 65(c) bond and thus facilitated and fostered the expeditious resolution of their patent infringement dispute; (2) it protected HMRI's patent rights and provided Andrx with capital to invent around the '584 patent and thus allowed Andrx an opportunity to enter in the market sooner without the risk of patent liability; and (3) it provided Andrx with an opportunity to obtain a license from HMRI that, if exercised, would allow Andrx to enter the market and compete with HMRI without the risk of patent liability both while the suit was pending (in January 2000, 18 months after Andrx's ANDA obtained FDA approval) and in the event Andrx lost the HMRI/Andrx patent suit. The Court addresses each of these in turn.

First, Defendants' claims that the HMRI/Andrx Agreement merely "settled" HMRI's claim for injunctive relief and maintained the status quo lack merit. The HMRI/Andrx Agreement did not maintain the status quo. HMRI's interim payments to Andrx in the amount of $10 million per quarter negate this claim. More importantly, the restraints imposed by the Agreement exceed those generally available under a court-ordered preliminary injunction: (1) it barred Andrx's entry into the market beyond resolution of the HMRI/Andrx patent suit in the district court; (2) it provided large interim payments to Andrx that created an incentive for Andrx to stay off the market with its generic drug after obtaining FDA

approval in contrast to a Rule 65(c) bond, issued at the Court's discretion, to cover damages actually incurred if HMRI was successful in obtaining a preliminary injunction but ultimately unsuccessful in its infringement action; (3) it barred Andrx from relinquishing or compromising its right to the 180-day period of exclusivity it obtained under the Hatch-Waxman Amendments and, in contrast to a court-ordered Rule 65(c) bond, provided large interim payments to Andrx that created an incentive for Andrx not to withdraw, relinquish or otherwise compromise its right to the 180-day period of marketing exclusivity; and (4) it barred Andrx from marketing other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending HMRI/Andrx patent case, including the reformulated generic drug described in Andrx's September 11, 1998 prior approval supplement to its ANDA No. 74-752.[14]

---

[14] HMRI had available the entire 30-month waiting period under Hatch-Waxman in which to seek an injunction. Andrx could not enter the market until that two and one-half year period expired, but HMRI did not seek any such relief in the HMRI/Andrx patent action. Had HMRI sought and obtained injunctive relief, it would have obtained *Noerr-Pennington* immunity, protected its patent, and could have sought a Rule 65(c) bond that, most likely, would not require it to pay interim quarterly payments to Andrx in the amount of $10 million. HMRI, however, did not seek an injunction.

Unlike a court-ordered preliminary injunction, this Agreement was never presented to, filed in, or approved by the court presiding over the HMRI/Andrx patent case. The restraints embodied in the HMRI/Andrx Agreement are the result of a purely private agreement and, as this Court has previously determined, are not immune from antitrust liability under the *Noerr-Pennington* doctrine. *See* Order No. 12, Mem. Op. & Order Denying Defendants' Motions to Dismiss at 25-45. Here, there was no judicial finding that HMRI was likely to succeed on the merits of its infringement suit, that HMRI would suffer irreparable injury, that a balancing of the equities and consideration of the public's interest weighed in favor of granting a preliminary

Contrary to Defendants' arguments here, the HMRI/Andrx Agreement did not resolve the pending patent claims; the only claims it resolved were Andrx's antitrust and unfair practice claims against HMRI. Rather than facilitating or fostering an expeditious resolution of the HMRI/Andrx patent infringement suit, the Agreement required Andrx to diligently prosecute its ANDA, the very act of infringement that triggered the HMRI/Andrx patent suit. The $10 million quarterly payments also created the incentive to pursue the litigation beyond the district court and through the appellate courts by extending those interim payments until entry of a final and unappealable order or judgment.

Likewise unavailing are Defendants' arguments that the Agreement merely protected HMRI's patent rights

---

injunction in HMRI's favor, and that a Rule 65(c) bond was warranted in an amount equal to the amounts to be paid out under the HMRI/Andrx Agreement. Rather than seeking an injunction from the court, the parties agreed to keep the terms and existence of the Agreement confidential and further agreed that the Agreement, any drafts, or supporting documents were not to be introduced into evidence in the pending HMRI/Andrx patent action or any other litigation.

As one commentator has observed, "[w]ere one competitor to agree to pay, and to pay, another to leave a business in order to eliminate its competition, all would accept that ordinarily there had been a per se antitrust violation. A similar anti-competitive result can be achieved, in a more innocent-appearing manner, if the patent owner pays money, or gives an infringer some thing of value, to be subject to a patent injunction, especially if the injunction is broader than the claims. Ordinarily, consideration flows the other way; the infringer pays some amount to the patent owner for past infringement and then agrees to be subject to an injunction for the remaining life of the patent, or is granted a license." Robert J. Hoerner, *Antitrust Pitfalls in Patent Litigation Settlement Agreements*, 8 Fed. Circuit B.J. 113, 122 (Summer 1998). "If the patent owner pays the infringer, and if the infringer settles by accepting an injunction, or agrees to abandon the field, scrutiny is warranted." *Id.* at 123.

and provided Andrx with capital to invent around the '584 patent thus allowing Andrx an opportunity to enter the market sooner without the risk of patent liability. The Agreement barred Andrx from marketing not only the Andrx Product but also other bioequivalent or generic versions of Cardizem CD. *See* HMRI/Andrx Agreement at ¶ 2(A). Moreover, the Agreement defines the "Andrx Product" to include not only the product described in Andrx's original ANDA No. 74-752 but also the product described in any amendment or modification to Andrx's ANDA No. 74-752 not requiring withdrawal of that ANDA or submission of a new ANDA. *Id.* at ¶ 8(B)(iv). The Agreement thus barred Andrx from marketing non-infringing or potentially non-infringing versions of Cardizem CD, including the reformulated generic drug described in Andrx's September 11, 1998 prior approval supplement to its ANDA No. 74-752. Therefore, even assuming that the interim quarterly payments under the Agreement provided Andrx with capital to invent around the '584 patent, the terms of that Agreement still barred Andrx's entry into the market with that reformulated product.

Finally, the Court disagrees with Defendants' arguments that the Agreement's provisions providing Andrx with an option to obtain a license and thus market Cardizem CD without any risk of patent liability make it susceptible to rule of reason rather than *per se* analysis. The Agreement did provide Andrx with an opportunity to obtain a license from HMRI that, if exercised, would allow it to enter the market without the risk of patent liability both while the patent suit was still pending (in January 2000) and in the event Andrx ultimately lost the HMRI/Andrx patent suit. Consideration of the plain language of the HMRI/Andrx Agreement, its restraints and its likely effects, however, lead the Court to conclude

that the option to lease and other allegedly pro-competitive provisions of the Agreement do not preclude analysis under the *per se* rule. The Court is not convinced that the restraints embodied in the HMRI/Andrx Agreement are merely ancillary to the allegedly competition-enhancing provisions of that Agreement. Rather, the clear and unambiguous terms of the Agreement indicate that its main thrust was to have Andrx refrain from going to market with its generic version of Cardizem CD beyond the July 8, 1998 date when it could have entered the market, and to have Andrx continue the prosecution of its ANDA (the alleged infringing act) and not otherwise compromise its right to the 180-day exclusivity period (which would delay the entry by others with generic versions of Cardizem CD because, under the scheme of the Hatch-Waxman Amendments, these potential generic competitors would be forced to wait out this exclusivity period before obtaining FDA approval), and to have HMRI pay Andrx tens of millions of dollars as long as Andrx complied. The HMRI/Andrx Agreement, on its face, allocates the entire U.S. market for Cardizem CD and its bioequivalents to HMRI for the life of that Agreement. Accordingly, this Court concludes that it is a naked horizontal market allocation agreement and thus constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act and under the various state antitrust laws at issue here.

As the Supreme Court recently observed, it has "reiterated time and time again that '[h]orizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition.' Such limitations are per se violations of the Sherman Act." *Palmer*, 498 U.S. at 49 (quoting *Topco*, 405 U.S. at 608). The Court has further observed that, although § 1 of the Sherman Act "prohibits only agreements that *unreasonably*

restrain trade", "certain kinds of agreements will so often prove so harmful to competition and so rarely prove justified that the antitrust laws do not require proof that an agreement of that kind is, in fact, anti-competitive in the particular circumstances." *NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 133, 119 S. Ct. 493, 497 (1998). "An agreement of such a kind is unlawful *per se*." *Id.* (citing *Palmer* for the position that horizontal market allocation agreements are *per se* illegal). Accordingly, once the Court decides that an agreement is a kind that is unlawful *per se*, then it becomes irrelevant "whether or not [the Court] would decide this case the same way under the rule of reason." *Topco*, 405 U.S. at 609. Rather, "the Court has consistently rejected the notion that naked restraints of trade are to be tolerated because they are well intended or because the are allegedly developed to increase competition." *Id.* at 610.

4. HMRI/Andrx Agreement's Effect on the Price of Cardizem CD

The Court rejects Defendants' arguments that the Court cannot consider the HMRI/Andrx Agreement's practical effect on the price of Cardizem CD. The anti-competitive effect of the HMRI/Andrx Agreement is obvious on its face. It restricted competition between HMRI, the brand-name drug manufacturer, and Andrx, the generic drug manufacturer; allocated the entire U.S. market for Cardizem CD and its bioequivalents to HMRI; and allowed HMRI to maintain or fix the price of Cardizem CD at a non-competitive level during the life of the Agreement. The courts have observed that "the per se ban on price fixing is not limited to an express horizontal agreement setting a uniform price for a product or service. Rather, the Supreme Court jurisprudence on the subject teaches that the courts must look at the

challenged horizontal agreement's practical effect on price and competition" and the Court "has ruled repeatedly that price fixing does not have to be direct in order to be actionable." *Saint Francis Hosp.*, 94 F. Supp. 2d 399, 412, 2000 WL 370531 at **10-12 (citing and discussing *Socony-Vacuum Oil Co.*; *Nat'l Soc'y of Prof'l Engineers v. United States*, 435 U.S. 679, 693-94 (1978) (where the Supreme Court observed that agreements that interfere with the setting of prices by "free market forces" are illegal on their face and further observed that a ban on competitive pricing does not require an elaborate industry analysis to demonstrate its anti-competitive character); and *Catalano v. Target Sales, Inc.*, 446 U.S. 643, 648-49 (1980) (where the Supreme Court similarly observed that, although there was no direct agreement as to prices, "an agreement to terminate the practice of giving credit . . . falls squarely within the traditional *per se* rule against price fixing")). *See also Palmer*, 498 U.S. at 48-49 (observing that "explicit agreement on prices to be charged or that one party have the right to be consulted about the other's prices" was not necessary to constitute an illegal *per se* price fixing agreement).

V. Conclusion

For the foregoing reasons, Plaintiffs' motions for partial summary judgment are **GRANTED**. The Court concludes that Defendants' September 24, 1997 Agreement constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and under the various state antitrust laws at issue here.

By /s/ Nancy G. Edmunds
Nancy G. Edmunds
U.S. District Judge

Dated: 6/6/00

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 00-0113
Filed: December 12, 2000

In Re: CARDIZEM CD ANTITRUST LITIGATION;
MDL NO. 1278.

HOECHST MARION ROUSSEL, INC.,
ANDRX PHARMACEUTICALS, INC.,

Defendants-Petitioners.

B e f o r e :

DAUGHTREY and MOORE, *Circuit Judges*;
CARR, *District Judge.**

---

* The Honorable James G. Carr, United States District Judge of the Northern District of Ohio, sitting by designation.

ORDER

The defendants in this multidistrict antitrust litigation petition under 28 U.S.C. § 1292(b) for leave to appeal interlocutory orders of the district court denying their motions to dismiss the plaintiffs' complaints and granting the plaintiffs' motions for partial summary judgment. The plaintiffs oppose the petition. The defendants have filed a reply.

A motion has been filed by the Pharmaceutical Research & Manufacturers of America (PhRMA) for leave to file an amicus-curiae brief in support of the defendants' petition. The plaintiffs oppose the motion. The issues and arguments raised by the PhRMA in their tendered brief are the same as those contained in the defendants' petition, and we find no cause for granting their motion. *See* Fed. R. App. P. 29(b)(2).

Section § 1292(b) provides for discretionary appellate review of interlocutory orders certified by the district court as involving "a controlling question of law as to which there is substantial ground for difference of opinion" and an immediate appeal of which "may materially advance the ultimate termination of the litigation . . . ." *See Cardwell v. Chesapeake & Ohio Ry. Co.*, 504 F.2d 444, 446 (6th Cir. 1974); *Kraus v. Board of County Road Comm'rs for Kent County*, 364 F.2d 919, 922 (6th Cir. 1966). Upon consideration of the facts and arguments presented, we conclude that this case is appropriate for interlocutory review. *See Good Investment Promotions, Inc. v. Corning Glass Works*, 493 F.2d 891 (6th Cir. 1974). *See also Hill v. Henderson*, 195 F.3d 671, 678 (D.C. Cir. 1999) (certification under 28 U.S.C. § 1292(b)

by the transferee court in a multidistrict case of potentially outcome determinative rulings is favored).

The defendants' § 1292(b) petition is **GRANTED**. The PhRMA's motion for leave to file an amicus-curiae brief is **DENIED.**

ENTERED BY ORDER OF THE COURT

By /s/ Leonard Green
Clerk

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 00-2483
Filed: July 24, 2003

IN RE: CARDIZEM CD ANTITRUST LITIGATION
LOUISIANA WHOLESALE DRUG CO., ET AL.

Plaintiffs-Appellees,

—v.—

HOECHST MARION ROUSSEL, INC. and
ANDRX PHARMACEUTICALS, INC, ET AL.,

Defendants-Appellants.

Before:

SILER and CLAY, *Circuit Judges*;
and OBERDORFER, *District Judge*

ORDER

The court having received a petition for rehearing en banc, and the petition having been circulated not only to the original panel members but also to all other active judges of this court, and no judge of this court having requested a vote on the suggestion for rehearing en banc, the petition for rehearing has been referred to the original panel.

The panel has further reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision of the case. Accordingly, the petition is denied.

ENTERED BY ORDER OF THE COURT

By /s/ Leonard Green
Leonard Green, Clerk

Section 1 of the Sherman Act

15 U.S.C. § 1. Trusts, etc., in restraint of trade illegal; penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

21 U.S.C. § 355. New Drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. * * * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

* * * *

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

* * * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

* * * *

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the fac-

tual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

* * * *

(5)

* * * *

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

* * * *

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. * * * *

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

* * * *

35 U.S.C. § 154. Contents and term of patent; provisional rights

(a) In general.

(1) Contents. Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

* * * *

35 U.S.C. § 261. Ownership; assignment

Subject to the provisions of this title [35 USCS §§ 1 et seq.], patents shall have the attributes of personal property.

Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States. * * * *

35 U.S.C. § 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

* * * *

(e)

* * * *

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

* * * *

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

* * * *

(4) For an act of infringement described in paragraph (2)

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

* * * *

35 U.S.C. § 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. * * * *

35 U.S.C. § 284. Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title. * * * *

STIPULATION AND AGREEMENT

Stipulation and Agreement, dated September 24, 1997, between Hoechst Marion Roussel, Inc. and Carderm Capital L.P. (collectively, HMRI) and Andrx Pharmaceuticals, Inc. (Andrx);

WHEREAS, HMRI is the holder of United States patent No. 5,470,584 ('584 Patent), which patent HMRI asserts covers the controlled release diltiazem hydrochloride formulation which is marketed in the United States under the trademark Cardizem® CD; and

WHEREAS, Andrx has developed a controlled release diltiazem hydrochloride formulation which it asserts is bioequivalent to Cardizem® CD and, pursuant to 21 U.S.C. § 355(j), has submitted and amended an abbreviated new drug application (ANDA) to the United States Food and Drug Administration (FDA) in order to obtain the right to sell that product (the Andrx Product) in the United States; and

WHEREAS, HMRI has filed a Complaint against Andrx in the United States District Court claiming that the Andrx Product infringes the '584 patent, which case is pending in the Southern District of Florida as Case Number 96-06121 (the Patent Infringement Action); and

WHEREAS, both parties recognize that until the issues of whether the Andrx Product infringes the '584 patent and whether the '584 patent is valid and enforceable are resolved in a final and unappealable order or judgment (Final Judgment) each party could take actions during the pendency of the Patent Infringement Action which could have significant financial repercussions; and

WHEREAS, HMRI believes that the market for diltiazem hydrochloride and the consumers of diltiazem

hydrochloride could be harmed in the event that an infringing or non-bioequivalent product were brought to market; and

WHEREAS, HMRI has asserted that it intends to seek an injunction barring the marketing, distribution or sale of the Andrx Product prior to the entry of Final Judgment on HMRI's claims in the Patent Infringement Action; and

WHEREAS, HMRI has also asserted that it intends to seek substantial damages and trebled damages for any marketing of the Andrx Product before the entry of Final Judgment; and

WHEREAS, Andrx recognizes that it could lose a substantial investment were it to move forward to market the Andrx Product following the date on which the FDA's approval of the Andrx Product under 21 U.S.C. § 355(j) becomes effective (FDA Approval) but before the entry of Final Judgment and were HMRI successful in obtaining an injunction blocking the distribution and sale of the product; and

WHEREAS, Andrx also recognizes that the damages could be potentially ruinous were Andrx to bring the Andrx Product to market and were HMRI to prevail in the Patent Infringement Action; and

WHEREAS, Andrx also believes that if it were to refrain from selling the Andrx Product until after Final Judgment is rendered in the Patent Infringement Action and it prevails in the Patent Infringement Action, then it will have lost substantial revenues from the Andrx Product; and

WHEREAS, Andrx is desirous of bringing a bioequivalent or generic form of Cardizem® CD to the market; and

WHEREAS, the parties intend to fully and vigorously litigate the infringement and validity issues underlying the Patent Infringement Action, but wish to reduce the risks and losses which could result from an adverse decision with respect to damages.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, and the mutual covenants set forth herein, the parties agree as follows:

1. *Effect of Recitals*:

The recitals set forth above are true and correct and are incorporated herein by reference.

2. *Obligation to Maintain Status Quo*:

(A). Pending the entry of Final Judgment, the parties agree to maintain the status quo with respect to the commercial sale of the Andrx Product in the United States. Andrx agrees not to commence the commercial sale of the Andrx Product or other bioequivalent or generic version of Cardizem® CD in the United States directly or indirectly until the entry of Final Judgment, or until it obtains a license from HMRI pursuant to paragraphs 5, 6, and 7 of this Stipulation and Agreement, or until Andrx receives the notice required by Paragraph 5 of this Stipulation and Agreement, whichever is the first to occur. Andrx further agrees that during the pendency of the Patent Infringement Action, it will diligently prosecute the ANDA for the Andrx Product and will not relinquish or otherwise compromise any right accruing thereunder or pertaining thereto.

(B). HMRI agrees not to seek further preliminary injunctive relief against Andrx in this litigation or otherwise until the entry of Final Judgment. HMRI further

agrees that for the period beginning on April 1, 1998 and ending upon the termination of this Stipulation and Agreement or the termination of any licensing agreement entered hereunder, whichever is later, HMRI will provide Andrx with a copy of any changes it proposes to the FDA with respect to the package insert and the immediate container label for Cardizem® CD within 10 days of the date upon which such proposed changes are transmitted to the FDA. HMRI further agrees that it will notify Andrx of any proposed changes which may be pending before the FDA as of April 1, 1998. HMRI further agrees to notify Andrx in writing of any labeling change which is approved by the FDA with respect to Cardizem® CD within 10 days of receiving notification of such approval.

(C). Andrx agrees that it will dismiss, without prejudice, its antitrust and unfair competition counterclaims in the Patent Infringement Action (including but not limited to counts III through VI and counts XI through XV of said counterclaim) within 30 days of the execution of this Stipulation and Agreement. Andrx further agrees that as between the parties to this Stipulation and Agreement, such dismissal shall be with prejudice as of the date that Final Judgment becomes effective, provided that HMRI has fully complied with the terms of this Stipulation and Agreement.

(D). Both parties agree that neither will apply to the court in the Patent Infringement Action for an order increasing or decreasing the thirty (30) month period provided for by 21 U.S.C. § 355(j)(4)(B)(iii).

3. *Lost Profit Payments*:

(A). For the purposes of this Stipulation and Agreement, the parties stipulate that the profits that Andrx

would have realized from the sale of the Andrx Product would be $100 million per year after FDA Approval.

(B). If Final Judgment determines that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent, HMRI shall pay Andrx an amount, calculated at the stipulated rate of $100 million per year and prorated for fractions of a year, for the period beginning upon FDA Approval and ending on the date that Final Judgment becomes effective. (For the purposes of this Stipulation and Agreement, the Effective Date of Final Judgment shall mean the later of the date of final disposition in respect of said Final Judgment (or order, as the case may be) or the expiration of the period to appeal or seek review of said disposition, order or Final Judgment.) Said amount shall be reduced solely by an amount equal to the amounts actually paid to Andrx by HMRI pursuant to Paragraph 4(A) below.

(C). In the event that HMRI provides Andrx with notice pursuant to Paragraph 5(B) of this Stipulation and Agreement, the end of the period described in Paragraph 3(B) above shall be the earlier of: (1) the date Andrx effects its first commercial sale of the Andrx Product; or (2) the date HMRI or its licensee effects its first commercial sale of a generic or bioequivalent form of Cardizem® CD, provided that the first such sale by HMRI or its licensee occurs after the expiration of the notice period described in Paragraph 5(B).

(D). In the event that Andrx exercises its option to acquire a license pursuant to Paragraph 6 (A)(ii) of this Stipulation and Agreement, the end of the period described in Paragraph 3(B) above shall be the date upon which said license agreement becomes effective.

(E). Andrx shall prepare and forward an invoice for the amount due from HMRI pursuant to this Paragraph and that invoice shall be payable and paid to Andrx within 30 days of the date of the invoice.

4. *Interim Payments*:

(A). For the period beginning upon FDA Approval and ending on the Effective Date of Final Judgment, Andrx shall be entitled to receive nonrefundable interim payments from HMRI of $40 million per year, payable quarterly. Within 10 days after FDA Approval, HMRI shall pay to Andrx a prorated amount for the period between that effective date and the end of that calendar quarter. On the first day of each calendar quarter after that effective date, HMRI shall pay to Andrx the full $10 million quarterly payment due to Andrx under this Paragraph.

(B). In the event that HMRI provides Andrx with notice pursuant to Paragraph 5(B) of this Stipulation and Agreement, the end of the period described in Paragraph 4(A) shall be the date upon which the applicable written notice period described in Paragraph 5(B) expires or the date Andrx effects its first commercial sale of the Andrx Product, whichever is earlier.

(C). In the event that Andrx exercises its option to acquire a license pursuant to Paragraph 6 (A)(ii) of this Stipulation and Agreement, the end of the period described in Paragraph 4(A) above shall be the date upon which said license agreement becomes effective.

5. *License*:

HMRI hereby grants, and warrants it has the right to grant, to Andrx an irrevocable option to acquire a license (or sublicense as the case may be) to all intellectual property which HMRI owns or controls that Andrx may need to sell, market and distribute the Andrx Product in the United States, its territories and possessions, including the Commonwealth of Puerto Rico. (HMRI agrees that it shall not sell, assign or otherwise voluntarily divest itself of said intellectual property during the term of this Stipulation and Agreement in a way which would interfere with or otherwise frustrate Andrx's right to acquire a license under either Paragraphs 5 or 6 of this Stipulation and Agreement.) Such license shall be non-exclusive.

(A). In the event that Andrx previously has taken a license under Paragraphs 6(A)(i) or 6(A)(ii) of this Stipulation and Agreement, HMRI shall have no obligation to notify Andrx of HMRI's intention to either license said intellectual property to any other party (either directly or indirectly, including, but not limited to, an agreement not to enforce said intellectual property against the other party) for the purposes of selling a bioequivalent or generic version of Cardizem® CD or utilize said intellectual property (directly or through a subsidiary) for the purpose of selling its own bioequivalent or generic version of Cardizem® CD in its own right.

(B). In the event that Andrx has not taken a license under Paragraphs 6(A)(i) or 6(A)(ii) of this Stipulation and Agreement and HMRI elects to either license said intellectual property to any other party (either directly or indirectly, including, but not limited to, an agreement not to enforce said intellectual property against the other

party) for the purposes of selling a bioequivalent or generic version of Cardizem® CD or utilize said intellectual property (directly or indirectly through a subsidiary or any other entity) for the purpose of selling its own bioequivalent or generic version of Cardizem® CD in its own right, then HMRI shall give Andrx written notice prior to the date upon which the third party licensee is authorized to make its first commercial sale or the date of HMRI's first commercial sale as required in the following schedule:

(i). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises on or before July 1, 1998—360 days prior written notice is required.

(ii). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises after July 1, 1998 and on or before December 31, 1998—180 days prior written notice is required.

(iii). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises on or after January 1, 1999 and on or before March 31, 1999—120 days prior written notice is required.

(iv). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises on or after April 1, 1999 and on or before June 30, 1999—90 days prior written notice is required.

(v). If the date upon which the third party licensee is authorized to make its first commercial

sale or HMRI's first planned sale arises after June 30, 1999—30 days prior written notice is required.

(C). The notice provided in Paragraph 5(B) above shall identify, by name, the third party licensee or the HMRI entity authorized to sell a bioequivalent or generic version of Cardizem® CD and shall specify the date upon which the third party licensee is authorized to make its first commercial sale or the date HMRI's first commercial sale is contemplated.

(D). Except as expressly provided in this Stipulation and Agreement, HMRI expressly retains all rights under said intellectual property.

6. *Time to Exercise Option to Obtain License*:

(A). The option referred to in Paragraph 5 above must be exercised, if at all, at one of the three opportunities set forth below.

(i) By no later than the period beginning on the Effective Date of Final Judgment and ending 30 days thereafter.

(ii) In the event that Final Judgment is not entered before the earlier of:

(a) a date 18 months following FDA Approval; or,

(b) the date upon which FDA approval for a third party to make and market a bioequivalent or generic version of Cardizem® CD becomes effective.

Andrx may exercise said option at any time beginning on the earlier of these dates and end-

ing on the date 30 days after the Effective Date of Final Judgment.

(iii) In the event that HMRI notifies Andrx of its intent to license said intellectual property to any other party for the purposes of selling a bioequivalent or generic version of Cardizem® CD, or of its intent to use said intellectual property (directly or indirectly through a subsidiary or any other entity) for the purpose of selling its own bioequivalent or generic version of Cardizem® CD, Andrx may exercise said option at any time beginning on the date it receives said notification and ending on the Effective Date of Final Judgment.

(B). Except as regards the license fees and royalty rates set forth below, the terms of the license shall be negotiated in good faith by the parties and shall allow Andrx to sell the Andrx Product as a bioequivalent or generic version of Cardizem® CD. Andrx shall be authorized to sell the Andrx Product during such negotiations and prior to the execution of a formal license agreement.

7. *License Fee and Royalties*:

As set forth below, Andrx agrees to pay HMRI a license fee at the time it acquires a license pursuant to this Stipulation and Agreement as well as royalties based upon the "net receipts" based upon the sales of the licensed products. For the purpose of this Stipulation and Agreement and of any license entered into by the parties pursuant to this Stipulation and Agreement, the term "net receipts" shall mean gross receipts less deductions relating to returns, shelf stock allowances, discounts, rebates and similar adjustments.

(A). In the event that Andrx acquires the license pursuant to Paragraph 6(A)(i) of this Stipulation and Agreement, the license fee is $60 million and the royalty is 20% on net receipts.

(B). In the event that Andrx acquires the license pursuant to Paragraph 6(A)(ii) or Paragraph 6(A)(iii) of this Stipulation and Agreement, the initial license fee is $30 million and the royalty is 10% on net receipts collected prior to the Effective Date of Final Judgment.

(i). If Final Judgment determines that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent, HMRI shall refund said license fee by paying to Andrx $30 million and shall refund all royalty payments made to HMRI by Andrx under the license within 30 days of the Effective Date of said Final Judgment, and the license shall be terminated on the Effective Date of Final Judgment.

(ii). Unless Final Judgment determines that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent, Andrx shall pay HMRI an additional license fee of $30 million within 30 days of the Effective Date of Final Judgment and thereafter pay HMRI a royalty of 20% on net receipts.

8. *Final Judgment and Termination*:

(A). In the event that HMRI dismisses the Patent Infringement Action prior to the Effective Date of Final Judgment, such dismissal shall be deemed to be as between the parties to this Stipulation and Agreement, a Final Judgment that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe

said patent and said Final Judgment will be deemed to be effective on the date 90 days following the date upon which such dismissal becomes effective. HMRI agrees that such dismissal shall be with prejudice and shall eliminate HMRI's right to refile such an action pursuant to Paragraph 8(C). If Andrx has taken a license under either Paragraph 6(A)(ii) or 6(A)(iii) of this Stipulation and Agreement, Andrx's obligation to pay royalties under the license shall terminate as of the date such dismissal is entered (not the deemed Effective Date of Final Judgment), and Paragraph 7(B)(i) shall apply and Paragraph 7(B)(ii) shall not apply.

(B). It is understood by the parties that in addition to the specific obligations set forth in Paragraph 2 of this Stipulation and Agreement, Andrx agrees that it may not transfer, sell or assign any right to obtain a license pursuant to Paragraphs 5 and 6 of this Stipulation and Agreement or any rights granted to Andrx pursuant to a license issued under said paragraphs to any other party without the express written consent of HMRI (a change in the ownership or control of Andrx's stock shall not require HMRI's consent), and, subject to subparagraph (iv) below, Andrx may not, prior to the Effective Date of Final Judgment, withdraw the ANDA that it has submitted to the FDA for the Andrx Product.

(i). In the event that Andrx violates its obligations under Paragraph 2; transfers, sells or assigns any rights granted to Andrx by HMRI pursuant to Paragraphs 5 and 6 of this Stipulation and Agreement or pursuant to any license issued under said paragraphs to any other party without the express written consent of HMRI (a change in the ownership or control of Andrx's stock shall not require HMRI's consent), or, prior to the Effective Date of

Final Judgment, withdraws the ANDA that it has submitted for the Andrx Product, then Andrx shall pay HMRI an amount equal to the amount of all payments that have been paid to Andrx pursuant to this Stipulation and Agreement, and this Stipulation and Agreement shall be terminated.

(ii). Before HMRI may seek termination of this Stipulation and Agreement and the return of monies paid to Andrx pursuant to this Subparagraph 8(B)(i), HMRI shall provide express written notice to Andrx specifying the obligation which, in HMRI's opinion, Andrx has not fulfilled, the specific manner in which each such obligation has not been fulfilled, and the specific conduct by Andrx that, in HMRI's opinion, will cure the asserted default. In the event that Andrx cures the alleged non-fulfillment identified by HMRI within 30 days of receiving such notice (or such other longer period as HMRI in writing expressly consents), such cure will be deemed full compliance (retroactive to the date of the first asserted default) and this Stipulation and Agreement will remain in full force and effect.

(iii). If Andrx has taken a license under either Paragraphs 6(A)(ii) or 6(A)(iii) of this Stipulation and Agreement, termination of this Stipulation and Agreement as contemplated under Paragraph 8(B)(i) shall not terminate any license previously granted to Andrx pursuant to Paragraph 5 and, with respect to license fees and royalty payments, Paragraph 7(B)(ii) shall apply and Paragraph 7(B)(i) shall not apply.

(iv). Nothing in this Stipulation and Agreement shall be construed as prohibiting or limiting Andrx's

right to amend or modify the ANDA that it has filed with respect to the Andrx Product so long as such amendment or modification shall not require the withdrawal of the existing ANDA and/or submission of a new ANDA and shall otherwise be consistent with Andrx's obligation to diligently prosecute its ANDA before the FDA as set forth in Paragraph 2 of this Stipulation and Agreement. For all purposes of this Stipulation and Agreement the term "Andrx Product" shall mean the product Andrx intends to sell pursuant to the ANDA on file with the FDA and as said ANDA may be amended consistent with this subparagraph.

(C). Notwithstanding any other provision of this Stipulation and Agreement, in the event that there is a final unappealable determination in the Patent Infringement Action that does not determine either (1) that the '584 Patent is valid and enforceable and the Andrx Product infringes said patent; or (2) that the '584 patent is invalid or unenforceable and/or that the Andrx Product does not infringe said patent, such determination shall be deemed to constitute, for all purposes in this Stipulation and Agreement, a Final Judgment that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent unless HMRI notifies Andrx in writing within 30 days of the date of such determination that it continues to believe that the Andrx Product infringes the '584 Patent and that it will seek to enforce the '584 patent by refiling its action at an appropriate time in an appropriate forum and refiles its action no later that 30 days following the later of either: (1) FDA Approval; or, (2) the date upon which the final unappealable determination referenced above in this Paragraph is entered. Andrx agrees that it will not seek to

block or otherwise frustrate HMRI's efforts to refile its action in this manner in a timely fashion provided that nothing herein shall be deemed to constitute a waiver by Andrx of any defenses, including the defense of preclusion, that it may have available in such refiled action. In the event HMRI provides the notice set forth above and refiles its action within the time frames herein established, such renewed action shall constitute the Patent Infringement Action for the purposes of the Stipulation and Agreement and the parties' respective obligations and rights under this Stipulation and Agreement shall continue uninterrupted and unimpaired as though no final, unappealable determination had been entered. In the event HMRI does not provide the notice set forth above or does not refile its action within the time frames herein established, Final Judgment shall be deemed to have been entered on the expiration of the period for HMRI to issue such notice, if it has not done so, or the expiration of the period in which it was required to refile such action if notice was provided, and for the purposes of this Stipulation and Agreement, such date shall be deemed as the Effective Date of Final Judgment. In the event that Final Judgment is deemed entered pursuant to this paragraph, it shall, as between the parties to this Stipulation and Agreement, constitute a final conclusive and unappealable determination that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent.

(D). Notwithstanding any other provision of this Stipulation and Agreement, in the event that prior to a Court determining the issues of the validity of the '584 patent and whether the Andrx Product infringes that patent, Andrx in writing stipulates or, in open court and on the record, concedes that the '584 patent is valid and that the Andrx Product infringes said patent, Andrx shall

repay to HMRI an amount equal to the amount of all payments that have been paid to Andrx pursuant to this Stipulation and Agreement, and this Stipulation and Agreement shall be terminated.

9. *Use of Agreement*:

Except as otherwise required by law or as otherwise may be requested by the court in the Patent Infringement Action, the terms and existence of this Stipulation and Agreement shall be kept confidential. This Stipulation and Agreement and any drafts thereof or any documents or records pertaining thereto or information derived therefrom shall not be introduced into evidence in the Patent Infringement Action or any other litigation for any purpose.

10. *Effect of Agreement*:

The parties represent and warrant that this Stipulation and Agreement constitutes their valid and legally binding obligations and shall be binding upon and inure to the benefit of the parties hereto and their successors and assigns. Except as otherwise provided in Paragraph 8(B), this Stipulation and Agreement may not be assigned without the express written consent of the other party. However, nothing in this Paragraph or this Stipulation and Agreement shall restrict Andrx's right to assign its right to receive income under this Stipulation and Agreement.

11. *Applicable Law - Consent to Jurisdiction*:

The parties hereto expressly agree that all the terms and provisions hereof shall be construed under the laws of the State of Florida as now adopted or as may be hereafter amended, without giving effect to any conflict

of law or choice of law provision or rule. In the event of a dispute between the parties as to the interpretation, application or effect of this Stipulation and Agreement, the parties agree that any litigation arising out of such dispute shall be filed and venue shall be conclusively laid in the United States District Court for the Southern District of Florida, and both parties expressly consent to personal jurisdiction in that forum for the purposes of resolving said dispute.

12. *Entire Agreement*:

This Stipulation and Agreement constitutes the entire agreement of the parties hereto with respect to the matters set forth herein and supersedes any prior understanding or agreement, oral or written, with respect thereto.

13. *Nonpayment*:

Any amounts not paid when due shall thereafter bear interest at 18% per annum and all costs and expenses, including reasonable attorneys' fees, incurred in connection with the enforcement of this Stipulation and Agreement shall be paid to the prevailing party by the nonprevailing party, upon demand.

IN WITNESS WHEREOF, the parties hereto have caused this Stipulation and Agreement to be executed by their duly authorized representatives on the date first written above.

Hoechst Marion Roussel, Inc.

By /s/ Peter W. Ladell

Name Peter W. Ladell

Title Chief Operating officer

Andrx Pharmaceuticals, Inc.

By /s/ Chih-Ming J. Chen

Name Chih-Ming J. Chen, Ph.D.

Title President

Carderm Capital L.P.

By /s/ Dirk Kruse

Name Dirk Kruse

Title Authorized Representative

UNITED STATES COURT OF APPEALS
For the Eleventh Circuit

No. 00-2483

VALLEY DRUG COMPANY, LOUISIANA WHOLESALE DRUG COMPANY, INC. ET AL.,

Plaintiffs-Appellees,

—v.—

GENEVA PHARMACEUTICALS, INC., ABBOTT LABORATORIES

Defendants-Appellants.

Appeal from the United States District Court
for the Southern District of Florida.

No. 02-12091.

Decided and Filed: September 15, 2003

Before:

TJOFLAT and ANDERSON, *Circuit Judges*;
STAFFORD, *District Judge*.

This case comes to us on interlocutory appeal from the district court's order granting plaintiffs' motion for partial summary judgment. The issue with which we are presented is whether the district court properly determined that two agreements among the defendants were per se violations of § 1 of the Sherman Act, 15 U.S.C. § 1. Because we conclude that the district court incorrectly applied the law, the order below will be reversed and the case remanded for further proceedings consistent with this opinion.

I. BACKGROUND

This is a private antitrust lawsuit, or rather numerous private antitrust lawsuits, brought against three pharmaceuticals manufacturers. The various cases asserting antitrust injury from the actions of the defendants have been consolidated by the Judicial Panel on Multidistrict Litigation in the Southern District of Florida. Plaintiffs basically assert that two agreements, one between defendant-appellant Abbott Laboratories ("Abbott") and defendant-appellant Geneva Pharmaceuticals ("Geneva") and another between Abbott and defendant Zenith Goldline Pharmaceuticals ("Zenith"),[1] entered into in 1998, violated the Sherman Act's prohibition against contracts

[1] Zenith came to a tentative settlement following the district court's order granting partial summary judgment and is not a party to this appeal.

in restraint of trade. Abbott, a manufacturer of the pioneer drug Hytrin, entered separate agreements with generic manufacturers Zenith and Geneva while those companies were pursuing FDA approval of generic versions of Hytrin and while embroiled in patent litigation with those companies. Because the facts of this case took place against a complex regulatory background, we will first describe the relevant regulatory context, then the facts of the case as they appear in the current procedural posture, and then the relevant procedural history.

A. *Regulatory Framework*

No new drug can be marketed or sold in the United States without approval from the Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). Applications for FDA approval can be filed in one of two ways: as a new drug application ("NDA") under § 355(b), or as an abbreviated new drug application ("ANDA") under § 355(j). A new drug application must include exhaustive information about the drug, including reports of safety and efficacy studies. *See* 21 U.S.C. § 355(b)(1).

Prior to 1984, the NDA was the only method of obtaining FDA approval of a new drug. Every applicant had to submit safety and efficacy studies, even if such studies had already been performed for identical drugs or drugs with identical active ingredients. Adding to this inefficiency was the fact that the conduct of safety and efficacy studies would, if the new drug was the subject of a patent, constitute infringement of that patent under 35 U.S.C. § 271(a).[2] In an effort to eliminate these twin

[2] "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

impediments to the introduction of generic drugs to the market, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act. The primary accomplishments of the Hatch-Waxman Act were the creation of the ANDA, allowing a new drug applicant to piggyback on the safety and efficacy studies conducted for the pioneer drug, *see generally* 21 U.S.C. § 355(j); modification of the definition of infringement, so that the conduct of safety and efficacy studies for FDA approval is no longer infringing activity, *see generally* 35 U.S.C. § 271(e); and allowing the extension of patent terms to compensate for the period when a patented drug could not be marketed because it was undergoing the FDA approval process, *see generally* 35 U.S.C. § 156.

Several of Hatch-Waxman's additions to 21 U.S.C. § 355 govern FDA approval of ANDAs in the face of patent claims by pioneer drug makers. NDA applicants are required to submit the patent number and expiration date of any patent that a generic manufacturer might infringe.[3] If such a patent issues after approval of the NDA, the holder of the application is required to file the patent number and expiration date with the FDA no later than 30 days after the patent issues. *See* 21 U.S.C. § 355(c)(2). The FDA publishes this patent information, along with other information about the drug, in what is popularly known as the Orange Book. *See* 21 U.S.C. § 355(j)(7)(A).

An ANDA applicant relying on the safety and efficacy studies filed with the application of a drug listed in the

---

[3] Specifically, any patent claiming the drug or method of using the drug that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

Orange Book must make a certification with respect to each patent claiming the listed drug or a method of using the listed drug of which the applicant is aware. *See* 21 U.S.C. § 355(j)(2)(A)(vii). The applicant must certify either that (1) the patent information has not been filed with the FDA; (2) the patent is expired; (3) the patent will expire, identifying the expiration date; or (4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug. If the applicant certifies (1) or (2), FDA approval proceeds in regular fashion, *see* 21 U.S.C. § 355(j)(5)(B)(i); if the applicant certifies (3), the application will not be approved until the date the relevant patent expires, *see* 21 U.S.C. § 355(j)(5)(B)(ii).

If the ANDA applicant certifies that the relevant patents are invalid or will not be infringed, commonly called a "paragraph IV certification," several things happen. First, the applicant must notify the patent holder. 21 U.S.C. § 355(j)(2)(B). If the patent holder brings suit for patent infringement[4] within 45 days of receiving this notice, the FDA automatically delays approval of the ANDA for thirty months. *See* 21 U.S.C. § 355(j)(5)(B)(iii).[5]

---

[4] It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A). This definition of infringement was added by Hatch-Waxman to allow the invocation of the procedures described in the following paragraph of this opinion.

[5] The patent holder is, of course, free to sue the applicant for infringement under 35 U.S.C. § 271(e)(2)(A) after the 45 day window

If the court hearing the infringement action declares the patent invalid or not infringed, this automatic delay in FDA approval terminates, 21 U.S.C. § 355(j)(5)(B)(iii)(I), or, if the court finds the patent valid and infringed, the approval date will be set for a date on or after the patent's expiration, 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A). If the court grants the patent holder a preliminary injunction prior to the expiration of the 30-month stay, the application will be approved on the date on which the court later holds the patent invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(III).

The timing of FDA approval is affected by another provision of Hatch-Waxman in the event that a listed drug is subject to more than one paragraph IV certification. Approval of an ANDA that contains a paragraph IV certification is automatically delayed if another ANDA was previously filed based on the same listed drug and the previous ANDA contains a paragraph IV certification. Approval of the subsequent ANDA is delayed until 180 days after the earlier of (1) the first commercial marketing of the drug under the previous application or (2) the date a court hearing an infringement action brought against the previous filer holds the patent invalid or not infringed.[6] *See* 21 U.S.C. § 355(j)(5)(B)(iv). This delay-

---

expires. The 30-month stay of FDA approval, however, will not be triggered.

[6] When the agreements at issue were entered into, the FDA regulations defined the relevant court decision triggering the end of the 30-month stay or the start of the first filer's 180-day exclusivity period as the decision of the appellate court hearing the infringement action against the first filer. This rule was challenged in court and held invalid by *TorPharm Inc., v. Shalala*, No. 97-1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. Sep. 15, 1997), *appeal withdrawn and remanded*, 1998 U.S. App. LEXIS 4681 (D.C. Cir. Feb. 5, 1998), *vacated on other grounds* (D.D.C. April 9, 1998) (30-month stay expires upon judgment of the district court holding the patent not

ing mechanism gives the first generic manufacturer to file a paragraph IV certification and successfully challenge the scope or validity of a patent on a pioneer drug a 180-day period during which it is the exclusive competitor of the pioneer manufacturer. This exclusivity period is a significant incentive for generic manufacturers to challenge weak or narrow drug patents.

B. *Factual History*[7]

1. Zenith's and Geneva's ANDAs

Abbott manufactures Hytrin, a brand-name drug with the active ingredient dihydrate terazosin hydrochloride.[8]

---

infringed), and by *Mylan Pharms., Inc., v. Shalala*, 81 F. Supp. 2d 30 (D.D.C. 2000) (180-day exclusivity period triggered by judgment of the district court holding the patent invalid). Though the FDA was initially committed to continued adherence to the appellate judgment rule, *see* 62 Fed. Reg. 63,268 (Nov. 28, 1997), it dropped the rule following the *Mylan* decision, *see* 65 Fed. Reg. 43,233, 43,234 (July 13, 2000) (interim rule). The FDA now considers the 180-day exclusivity period to be triggered by any district court judgment holding the patent invalid, not infringed, or unenforceable, whether or not the judgment comes from the district court hearing the infringement suit against the first filer. *See Granutec, Inc., v. Shalala*, Nos. 97-1873 & 97-1874, 1998 WL 153410, *8-9 (4th Cir. April 3, 1998) (unpublished, table decision reported at 139 F.3d 889) (endorsing the FDA's position that, if the successful defense requirement is invalid, the court decision triggering the 180-day exclusivity period is the decision of any district court). *See also Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999) (reversing district court's denial of an injunction to require the FDA to recognize the dismissal with prejudice of an infringement suit against a subsequent filer as triggering the first filer's 180-day exclusivity period). *See post* at n.12 for a discussion of the successful defense requirement.

[7] The facts are largely uncontested by the parties.

[8] Terazosin hydrochloride is a crystal. Dihydrate terazosin hydrochloride is a particular crystalline polymorph of terazosin

Hytrin is used to treat hypertension and enlarged prostate, and has been a very successful product for Abbott. Abbott obtained FDA approval of its NDA for Hytrin in 1987 and has held a number of patents related to terazosin hydrochloride over the years. Its first patent, issued in 1977, covered the basic terazosin hydrochloride compound. *See Abbott Labs. v. Novopharm Ltd.*, Nos. 96-C-611 & 95-C-6657, 1996 WL 131498, *1 (N.D. Ill. March 15, 1996). That patent has since expired, though Abbott has been issued other patents for various crystalline forms of the compound and various methods of using and preparing the compound.

Geneva filed four ANDAs based on Hytrin between 1993 and 1996, each time making paragraph IV certifications with respect to Abbott's listed patents. Abbott brought infringement suits under 35 U.S.C. § 271(e), invoking the 30-month stay of FDA approval of Geneva's ANDAs. On April 29, 1996, Geneva filed two additional ANDAs based on Hytrin, one for a capsule form of terazosin hydrochloride and one for a tablet form[9], making paragraph IV certifications with respect to the relevant patents. Within 45 days of receiving notice of Geneva's paragraph IV certifications, Abbott filed an infringement suit based on the submission of the tablet ANDA, asserting that the Geneva's tablet terazosin hydrochloride product infringed Abbott's patent number 5,504,207 ("the '207 patent").[10] In the suit,

---

hydrochloride. The opinion will refer to terazosin hydrochloride and its polymorphs simply as terazosin hydrochloride unless greater specificity is appropriate.

[9] The active ingredient in these two drugs is anhydrous terazosin hydrochloride.

[10] The '207 patent, issued on April 2, 1996, claims a method of preparing anhydrous terazosin hydrochloride. The patent is due to expire in October of 2014.

Geneva admitted infringement but contested the patent's validity. Apparently through oversight, Abbott failed to file an infringement suit based on the submission of the capsule ANDA. FDA consideration of that ANDA, therefore, proceeded unhindered, and Geneva's capsule ANDA was approved in March of 1998. When Abbott was notified of this approval, it began efforts to amend its complaint to allege that Geneva's terazosin hydrochloride capsule infringed the '207 patent.

Zenith, meanwhile, filed an ANDA for a terazosin hydrochloride drug[11] in June of 1994, making a paragraph IV certification with respect to Abbott's Hytrin patents. Abbott was issued a patent claiming forms of terazosin hydrochloride on May 2, 1995, patent no. 5,412,095 ("the '095 patent"), and another on April 2, 1996, the '207 patent. Abbott timely filed this patent information with the FDA, which then required Zenith to amend its ANDA to make a certification with regard to these newly listed patents. Zenith resisted, hoping to avoid the 30-month stay of approval and the 180-day delay of approval based on Geneva's earlier-filed ANDAs.[12] Instead of certifying, Zenith brought suit

---

[11] The active ingredient of this drug is anhydrous terazosin hydrochloride.

[12] Prior to 1998, the FDA applied the "successful defense" requirement to ANDA filers hoping to take advantage of the 180-day exclusivity period. A subsequently-filed ANDA would only have its approval date delayed by 180 days if the first-filer had successfully defended against an infringement suit. *See* 59 Fed. Reg. 50,338, 50,367 (Oct. 3, 1994) (adopting successful defense regulation as a final rule, codified at 21 C.F.R. § 314.107). If Zenith's ANDA were ready for approval before Geneva successfully defended Abbott's infringement suit, then the ANDA would be approved without the 180-day delay. If Zenith were forced to make a paragraph IV certification with respect to Abbott's '095 and '207 patents, however,

against Abbott in an attempt to force Abbott to delist its '095 and '207 patents, relieving Zenith of the obligation to certify with respect to those patents, and seeking a declaration that its terazosin hydrochloride drug did not infringe those patents. Zenith's suit alleged that Abbott listed the '095 and '207 patents knowing that the patents did not claim Hytrin or a method of using Hytrin. Abbott counterclaimed for infringement. Zenith's attempt to obtain a preliminary injunction against the listing of the patents was unsuccessful. *See Zenith Labs. v. Abbott Labs.*, No. 96-1661, 1997 U.S. Dist. LEXIS 23954 (D.N.J. Oct. 1, 1997). Zenith appealed the denial to the Federal Circuit.

2. The Agreements

The agreements challenged by the plaintiffs arose against this backdrop. On March 31, 1998, Abbott and Zenith entered an agreement dismissing Zenith's delisting claims and Abbott's infringement counterclaims ("Zenith Agreement"). In the Zenith Agreement, Zenith acknowledged the validity of each of Abbott's patents claiming terazosin hydrochloride and admitted that any terazosin hydrochloride product Zenith might market would infringe these patents. Zenith agreed not to sell or distribute any pharmaceutical product containing any

---

Abbott could invoke the 30-month stay of approval, giving Geneva more time to defend Abbot's infringement action against it.

The successful defense requirement was eventually held to be an unreasonable interpretation of the Hatch-Waxman Act by two courts of appeals. *See Mova Pharm. Corp. v. Shalala*, 329 U.S. App. D.C. 341, 140 F.3d 1060, 1069-70 (D.C. Cir. 1998); *Granutec*, 1998 U.S. App. LEXIS 6685, 1998 WL 153410, at *6-7. The Mova court enjoined the FDA from enforcing the regulation, and the FDA dropped the requirement effective November 10, 1998. *See* 63 Fed. Reg. 59,710, 59,711 (Nov. 5, 1998) (interim rule).

form of terazosin hydrochloride until someone else introduced a generic terazosin hydrochloride product first or until Abbott's patent no. 4,215,532 (the '532 patent) expired.[13] Zenith agreed not to sell or transfer its rights under any ANDA application relating to a terazosin hydrochloride drug, not to aid any other person in gaining FDA approval of a terazosin hydrochloride drug, and not to aid any other person in opposing or invalidating any of Abbott's patents claiming terazosin. In return, Abbott agreed to a payment schedule according to which Abbott would pay Zenith $3 million up front, $3 million after three months, and $6 million every three months thereafter until March 1, 2000, or until the Agreement terminated by its own terms. If another generic manufacturer introduced a terazosin hydrochloride drug and obtained a 180-day exclusivity period, Abbott's payments would be halved until the period expired. Abbott agreed not to sue Zenith for infringement if it entered the market consistent with the Agreement.

Abbott entered an agreement with Geneva on April 1, 1998 ("Geneva Agreement"). According to the Geneva Agreement, Geneva agreed not to sell or distribute any pharmaceutical product containing any form of terazosin hydrochloride until either Abbott's '532 patent expired, someone else introduced a generic terazosin hydrochloride drug, or Geneva obtained a court judgment that its terazosin tablets and capsules did not infringe the '207 patent or that the patent was invalid. This latter condition required a final judgment from which no further appeal could be taken, including petition for certiorari to the Supreme Court. Geneva agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period. Geneva also agreed to

[13] The '532 patent claims dihydrate terazosin hydrochloride, the active ingredient in Hytrin. That patent expired on February 17, 2000.

oppose any subsequent ANDA applicant's attempt to seek approval of its application based on Geneva's failure to satisfy the then-existing successful defense requirement and to join and support any attempt by Abbott to seek an extension of the 30-month stay of FDA approval on Geneva's tablet ANDA. In return, Abbott agreed to pay Geneva $4.5 million each month until either someone else brought a generic terazosin hydrochloride product to market or Abbott won a favorable decision in the district court on its infringement claim. If Geneva won in district court, Abbott's $4.5 million monthly payments would go into escrow pending resolution of the appeal, with the escrowed funds going to the party prevailing on appeal. Abbott reserved the right to terminate its payments after February 8, 2000, if no other generic terazosin hydrochloride product had been marketed as of that date. If Abbott exercised this right, it would execute a release in Geneva's favor of any claims of infringement based on the '207 patent.

3. Termination of the Agreements

The district court hearing Abbott's infringement suit against Geneva handed down its decision on September 1, 1998. *Abbott Labs. v. Geneva Pharms., Inc.*, Nos. 96-C-3331, 96-C-5868, & 97-C-7587, 1998 WL 566884 (N.D. Ill. Sept. 1, 1998). The court held the '207 patent invalid because the crystalline form of terazosin hydrochloride claimed in the patent was on sale in the United States more than one year before Abbott applied for the patent, *see* 35 U.S.C. § 102(b). 1998 U.S. Dist. LEXIS 13864, 1998 WL 566884 at *7. Abbott appealed to the Federal Circuit, which affirmed on July 1, 1999. 182 F.3d 1315 (Fed. Cir. 1999). Abbott's petition for certiorari was denied on January 10, 2000. 528 U.S. 1078, 120 S. Ct. 796 (2000).

The Agreements did not terminate on their own terms, however. The parties terminated the Agreements on August 13, 1999, apparently in response to an FTC investigation of those Agreements. The FTC action resulted in a consent settlement. *See Matter of Abbott Labs.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000), *also available at* http://www.ftc.gov/os/2000/05/c3945.do.htm.

C. *Procedural History*

All class action and individual antitrust plaintiffs filed a joint motion for summary judgment that the Agreements were *per se* illegal under § 1 of the Sherman Act on February 18, 2000. The district court issued an order granting the motion on December 13, 2000. Permission to take an interlocutory appeal from the order under 28 U.S.C. § 1292(b) was granted on April 19, 2002.

D. *The Order Granting Summary Judgment*

The December 13, 2000, Order granting plaintiffs' motion for partial summary judgment concluded that the Agreements were *per se* violations of § 1 of the Sherman Act. The Order characterized the Agreements as geographic market allocation Agreements between horizontal competitors, essentially allocating the entire United States market for terazosin drugs to Abbott, who shared its monopoly profits with the other cartel members during the life of the Agreements.

The court found that on the eve of the Agreements,

> both Geneva and Zenith were poised to market generic versions of Hytrin in the United States. Geneva received final FDA approval for its generic capsule in March subject to "validation," and the 30-month stay on its generic tablet proposal was set

> to expire in October. Zenith declared that it was ready to market a generic tablet upon receipt of a favorable decision from the Federal Circuit and final FDA approval.

In re Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1345-46 (S.D. Fla. 2000). Despite being poised to enter the market, however, "Geneva and Zenith forswore competing with Abbott in the United States market for terazosin hydrochloride drugs . . . ." *Id.* at 1348-49.

The court identified four elements of the Agreement with Geneva that were anticompetitive: (1) Geneva's promise not to market its terazosin capsule until the Agreement terminated; (2) Geneva's promise not to market its terazosin tablet until the Agreement terminated; (3) Geneva's promise not to sell its rights in its capsule and tablet ANDAs until the Agreement terminated; and (4) Geneva's promise to aid Abbott in opposing any attempt by other ANDA applicants to enter the market before the Agreement terminated. The court identified three anticompetitive elements of the Agreement with Zenith: (1) Zenith's agreement to dismiss its delisting suit; (2) Zenith's promise not to aid any other entity's challenge to the validity of Abbott's terazosin patents; and (3) Zenith's promise not to market a generic terazosin product until the Agreement terminated. The essence of the Agreements, the court concluded, was to "dissuade[ ] Geneva and Zenith from marketing the first generic terazosin hydrochloride drugs in the United States for an indefinite period [and] eliminate the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim . . . ." *Id.* at 1349.

Despite holding the Agreements *per se* unlawful, the court nonetheless entertained, and rejected, the defendants' arguments that the Agreements were either pro-

competitive or benign.[14] Defendants argued that the Agreements eliminated the "substantial legal and financial risks" that accompany market entry while patent disputes remain unresolved. This justification was rejected for three reasons. First, the Agreement with Geneva was unnecessary to avoid these risks, because Geneva's unilateral decision to forego entry would achieve the same result. Second, the Agreement with Geneva did not resolve the patent litigation; "in fact, it tended to prolong that dispute to Abbott's advantage." *Id.* at 1350. The litigation was prolonged by the provisions extending the Agreement until the patent dispute was finally resolved, including Supreme Court review, and by Geneva's promise to aid Abbott in any motion seeking to extend the 30-month stay of FDA approval of Geneva's tablet ANDA. Finally, the court rejected the argument that the provision of the Agreement permitting Geneva to enter the market if Abbott elected to suspend its payments was pro-competitive. Although the court may have been willing to "infer that this clause was a catalyst for competition if Geneva paid Abbott for it, [ ] the suggestion that Abbott handsomely paid Geneva to spur competition in its own lucrative domestic market for ter-

---

[14] Defendants also argued that the Agreements were immune from antitrust liability under the *Noerr-Pennington* doctrine, *see United Mine Workers v. Pennington*, 381 U.S. 657, 85 S. Ct. 1585, 14 L. Ed. 2d 626 (1965); *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S. Ct. 523, 5 L. Ed. 2d 464 (1961); that the Agreements were not subject to *per se* treatment because of their novelty; and that the Agreements could not have anti-competitive effects because independent regulatory prohibitions prevented market entry by Geneva and Zenith until at least August of 1999. The court rejected these arguments, as well. The defendants do not raise their *Noerr-Pennington* or ineffective restraints arguments on appeal.

azosin hydrochloride products is patently unreasonable." *Id.* at 1351. The court did not analyze any potentially efficiency-enhancing effects of the Agreement with Zenith, concluding that the Agreement "would indefinitely postpone Zenith's entry into the United States market and would permit competition only once Abbott lost its exclusive market." *Id.*

Defendants argued that because the Agreement with Geneva was analogous to an interim patent settlement and the Agreement with Zenith terminated the litigation between Zenith and Abbott, the court should treat the Agreements as patent litigation settlements. The court rejected this argument as well, concluding that the Agreement with Geneva did not resolve Abbott's infringement suit and that the termination of litigation between Zenith and Abbott "was part of a larger scheme to restrain the domestic sale of generic terazosin hydrochloride products." *Id.* at 1353. Even if the Agreements were patent litigation settlements, the court held, such settlements were not immune from *per se* analysis. *Id.*

E. *Issues Appealed*

On appeal, Abbott and Geneva argue that the district court erred in concluding that the Agreements were per se violations of § 1 of the Sherman Act and that genuine issues of material facts remain in dispute.

Appellants argue that courts lack sufficient experience with agreements of the kind at issue to draw the conclusion that "history and analysis have shown that in sufficiently similar circumstances the rule of reason unequivocally results in a finding of liability." *Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1567 (11th Cir. 1991) (quotation and citation omitted). Appellants also argue that there are pro-competitive justifications

for the Agreements that warrant analysis under the rule of reason. Appellants argue that genuine issues of material fact are in dispute with regard to these potential procompetitive effects. Finally, Appellants argue that the Agreements are patent litigation settlements that must be analyzed under the rule of reason unless it is shown that the settlements were "sham."[15]

II. STANDARD OF REVIEW

We review a district court's grant of summary judgment de novo, applying the same legal standards applied by the district court. *Bailey v. Allgas, Inc.*, 284 F.3d 1237, 1242 (11th Cir. 2002). Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). We view the evidence in the light most favorable to the non-movant, resolving all reasonable doubts and drawing all reasonable inferences in that party's favor. *Bailey*, 284 F.3d at 1243.

III. DISCUSSION

Section 1 of the Sherman Act prohibits "every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations . . . ." 15 U.S.C. § 1. It is understood that the ban on "contract[s] in restraint of trade" means only unreasonable restraints, *State Oil Co. v. Khan*, 522 U.S. 3, 10, 118 S. Ct. 275,

---

[15] Indeed, all of appellants' arguments rely primarily on the circumstance that the Agreements arose in the context of patent litigation.

279 (1997), that is, restraints that impair competition, *Chicago Board of Trade v. United States*, 246 U.S. 231, 238, 38 S. Ct. 242, 244 (1918). Some types of agreements are so obviously anticompetitive, or so unlikely to be pro-competitive, that such agreements can be deemed to violate the Sherman Act without much more than an examination of the agreement itself and the relationships of the parties to the agreement. *State Oil*, 522 U.S. at 10, 118 S. Ct. at 279; *Arizona v. Maricopa County Medical Soc.*, 457 U.S. 332, 344, 102 S. Ct. 2466, 2473 (1982). These agreements are labeled "*per se*" violations. Regardless of terminology, the ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue. *National Collegiate Athletic Ass'n v. Bd. Regents Okla. Univ.*, 468 U.S. 85, 103, 104 S. Ct. 2948, 2962 (1984). The analytic focus should be on what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties. *See California Dental Ass'n v. FTC*, 526 U.S. 756, 779-81, 119 S. Ct. 1604, 1617-18 (1999), *NCAA*, 468 U.S. at 103-04, 104 S. Ct. at 2961-62.

The district court focused on the agreements by Geneva and Zenith not to enter the market with FDA-approved (or approval pending) generic terazosin drugs, holding that this exclusionary effect of the Agreements constituted an allocation of the market between horizontal competitors and that the Agreements were therefore *per se* illegal. We begin our discussion by addressing this exclusionary effect of the Agreements.

A.

An agreement between competitors to allocate markets is, as the district court noted, clearly anticompetitive. Such an agreement has the obvious tendency to diminish

output and raise prices. When a firm pays its only potential competitor not to compete in return for a share of the profits that firm can obtain by being a monopolist, competition is reduced. *See, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50, 111 S. Ct. 401, 403 (1990) (per curiam) (agreements not to compete within certain territorial limits are obviously anticompetitive); *United States v. Topco Assocs.*, 405 U.S. 596, 608, 92 S. Ct. 1126, 1133-34 (1972) (observing that an agreement between competitors to allocate territories is a "classic example" of a *per se* violation of the Sherman Act, with no purpose other than reducing competition).

If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent. For reasons explained below, and in light of the fact that all parties seem to agree that the ANDAs that were the subjects of the infringement suits infringed Abbott's '207 patent, we reject the district court's characterization of the instant Agreements as illegal *per se*. We believe any such characterization is premature without further analysis of the kind suggested in this opinion. Because the market allocation characterization was central to the district court's conclusion that the Agreements in their entireties are *per se* violations of § 1 of the Sherman Act, we will reverse the grant of summary judgment.

A patent grants its owner the lawful right to exclude others. *See* 35 U.S.C. §§ 271(a) (defining infringement) & 283 (providing injunctive relief for infringement); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S. Ct. 2601, 2623 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting

by the patented invention."). This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions. *Bonito Boats, Inc., v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51, 109 S. Ct. 971, 977-78, 103 L. Ed. 2d 118 (1989); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.C. Cir. 1981). The exclusionary right cannot be exploited in every way—patentees cannot pool their patents and fix the prices at which licensees will sell the patented article, for example, *see United States v. New Wrinkle, Inc.*, 342 U.S. 371, 72 S. Ct. 350 (1952)—but a patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself, *see, e.g., In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 2000); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1209 (2d Cir. 1981); or grant exclusive territorial licenses carving up the United States among its licensees, *see* 35 U.S.C. § 261. Within reason, patentees can also subdivide markets in ways other than territorial, such as by customer class. *Gen. Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175, 58 S. Ct. 849 *aff'd on reh'g*, 305 U.S. 124, 59 S. Ct. 116 (1938) (approving a license restricting the licensee's sales to non-commercial customers). Such arrangements undoubtedly tend to result in lower production and higher prices of the patented article than if competition were unrestrained, but these anticompetitive tendencies do not render them in violation of the Sherman Act.

The above discussion illustrates the point that a patentee's allocation of territories is not always the kind of territorial market allocation that triggers antitrust liability, and this is so because the patent gives its owner a lawful exclusionary right. In characterizing the Agree-

ments as territorial market allocations agreements, the district court did not consider that the '207 patent gave Abbott the right to exclude others from making, using, or selling anhydrous terazosin hydrochloride until October of 2014, when it is due to expire.[16] To the extent that Zenith and Geneva agreed not to market admittedly infringing products before the '207 patent expired or was held invalid, the market allocation characterization is inappropriate.

Zenith's agreement not to market an infringing generic terazosin hydrochloride drug terminated, by its own terms, when either another generic manufacturer marketed a terazosin product and any exclusivity period expired or Abbott's '532 patent expired in February of 2000. The effect of the Zenith Agreement on the production of Zenith's infringing terazosin product appears to be no broader than the potential exclusionary effect of the '207 patent, and was actually narrower to the extent it permitted Zenith to market its drug before the '207 patent expired. Geneva's agreement not to market an infringing terazosin product terminated at the earliest of (1) a final, unappealable judgment holding the '207 patent invalid; (2) the marketing of a terazosin product by another generic manufacturer; or (3) the expiration of the '532 patent. The effect of the Geneva Agreement on the production of Geneva's infringing generic terazosin product may have been no broader than the potential exclusionary effect of the '207 patent. The '207 patent may have allowed Abbott to obtain preliminary injunctive relief or a stay of an adverse judgment pending appeal, which also would have prevented Geneva from

---

[16] The '207 patent was, of course, declared invalid on September 1, 1998, a judgment affirmed on January 10, 2000. The antitrust consequences of this subsequent invalidation will be addressed below.

marketing its terazosin hydrochloride products during this period.[17]

With respect to the foregoing aspects of the two Agreements' exclusionary effects, which were the foundation of the district court's characterization of the Agreements as market allocation agreements, these are at the heart of the patent right and cannot trigger the *per se* label. [18] Unlike some kinds of agreements that are per se illegal whether engaged in by patentees or anyone else, such as tying or price-fixing, the exclusion of infringing competition is the essence of the patent grant. As one court has concluded, "when patents are involved . . . the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is *per se* illegal." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 249

---

[17] We say "may" because we do not hold that the '207 patent *would* have allowed Abbott to obtain a preliminary injunction or a stay of an adverse judgment pending appeal. We mean only that these are among the considerations that the district court should address on remand. We do note that appellees have not at this stage argued that Abbott would have been unable to obtain such relief.

[18] Appellees argue that the Agreements have broader exclusionary tendencies in that they also prohibited the marketing of non-infringing terazosin products, prohibited Geneva from marketing infringing products beyond the date a district court held the '207 patent invalid, and prohibited Geneva from waiving its 180-day exclusivity period. As we explain below, these prohibitions may be beyond the scope of Abbott's lawful right to exclude and, if so, would expose appellants to antitrust liability for any actual exclusionary effects resulting from these provisions that appellees can prove at the causation and damages stages of litigation. Our point thus far is that appellees have failed to prove that appellants should face *per se* antitrust liability for treble damages for the failure of Zenith and Geneva to market admittedly infringing products when no court had declared Abbott's patent invalid or unenforceable at the time of the Agreements.

(E.D.N.Y. 2003). Because the district court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis, its rationale was flawed and its conclusion that these Agreements constitute per se violations of the antitrust laws must be reversed.

While our holding at this early stage of the litigation is appropriately narrow, the decision below and the arguments of the parties invite our discussion of several matters that promise to be relevant on remand. We first discuss appellees' argument that the antitrust analysis need not consider Abbott's patent rights because the '207 patent was declared invalid. We then discuss appellees' argument that the lawful right of exclusion does not include the right to pay competitors not to produce infringing products. Finally, we offer several observations with respect to the framework to be developed on remand for deciding the appropriate antitrust analysis.

B.

The individual *Sherman Act* plaintiffs-appellees argue that because the '207 patent was declared invalid after the Agreements were entered into, Abbott never had any patent rights and our antitrust analysis need not consider the '207 patent. We reject the appellees' argument that the agreements by Geneva and Zenith not to produce infringing products are subject to *per se* condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid. We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into. *Polk Bros. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985); *SCM Corp.*, 645 F.2d at 1207. At the time the Agreements were entered into, no court had declared Abbott's '207 patent invalid, and the appellees have advanced no argument

other than mere invalidity.[19] We hold that the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis.

The right of exclusion conferred by a patent has been characterized as a defense to an antitrust claim, *see Walker Process Equip., Inc., v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179, 86 S. Ct. 347, 351 (1965) (Harlan, J., concurring), or as a limited exception to the general rule that markets should be free from barriers to competition, *see id.*, 382 U.S. at 176, 86 S. Ct. at 350; *United States v. Line Material Co.*, 333 U.S. 287, 309, 68 S. Ct. 550, 561 (1948); *id.*, 333 U.S. at 310, 68 S. Ct. at 562. Appellees' argument implies that this defense is unavailable with respect to the Agreements because the '207 patent was subsequently held invalid.

The only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced, it held that the antitrust claimant must prove that the patentee enforced a patent with the knowledge that the patent was procured by fraud on the Patent Office. *Walker Process*, 382 U.S. at 177, 86 S. Ct. at 350 (considering a monopolization claim against a patentee for suing to enforce a patent allegedly procured by fraud). Good faith procurement furnishes a complete defense to the antitrust claim. *Id.* Justice Harlan's concurrence explained that the effect of antitrust liability on the incentives for innovation and disclosure created by the patent regime must be taken

---

[19] That is, appellees have neither alleged nor asserted that the patent was procured by fraud, that appellants knew the patent was invalid, that there was no objective basis to believe that the patent was valid, or any such similar allegations. We therefore are not called upon to decide what the antitrust consequences of such circumstances might be.

into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws:

> It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in this area between the differing policies of the patent and antitrust laws. To hold, as we do, that private suits may be instituted under § 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. On the other hand, to hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits. Hence, this private antitrust remedy should not be deemed to reach § 2 monopolies carried on under a nonfraudulently procured patent.

382 U.S. at 179-80, 86 S. Ct. at 351-52. This approach is commonly used by courts considering the intersection of patent law and antitrust law. *See, e.g., SCM Corp.*, 645 F.2d at 1203-06 (considering antitrust claims against a patentee for acquiring and refusing to license various patents); *Handgards, Inc., v. Ethicon, Inc.*, 601 F.2d 986, 992-93 (9th Cir. 1979) (considering a monopolization claim against a patentee for asserting a patent it

allegedly knew to be invalid). A suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system is required by the complementary objectives of the two:

> It is commonly said . . . that the patent and antitrust laws necessarily clash . . . At the same time, the two regimes seek the same object: the welfare of the public . . . Antitrust law forbids certain agreements tending to restrict output and elevate prices and profits above the competitive level. Patent law also serves the interests of consumers by protecting invention against prompt imitation in order to encourage more innovation than would otherwise occur.

H. Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 1780a (1999) ("Hovenkamp") (citations and quotations omitted). *See also* D. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 Fla. L. Rev. 747, 748 n.1 (2002) ("It is generally recognized that antitrust and patent law, although polar opposites in their treatment of monopolies, share common objectives."); *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1352 (Fed. Cir. 1999) ("The patent and antitrust laws are complementary in purpose in that they each promote innovation and competition . . . .") (citation omitted).

Employing this approach, we conclude that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives. Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether

enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.[20] This uncertainty, coupled with a treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose. By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation. *See Ciprofloxacin*, 261 F. Supp. 2d at 256 (expressing concern for the effect of settlement-restricting antitrust liability rules on the incentives for research and development); *cf. Walker Process*, 382 U.S. at 180, 86 S. Ct. at 352 (Harlan, J., concurring) (permitting antitrust liability based on a showing mere invalidity "might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damages suits").

There may be circumstances under which the unreasonableness of a settlement agreement regarding a subsequently-invalidated or unenforceable patent would be

---

[20] The cost and complexity of most patent litigation is a familiar problem to the court system. *See, e.g., Blonder-Tongue*, 402 U.S. at 331-32 & 334-38, 91 S. Ct. at 1444 & 1445-48 ; *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1475-76 (Fed. Cir. 1998) (Rader, J., dissenting) (discussing claim construction); *Matter of Schering-Plough Corp.*, No. 9297, 2002 WL 1488085, *166-67 & *239-40 (F.T.C. June 27, 2002), *also available at* http://www.ftc.gov/os/caselist/d9297.htm. *See also* Crane, 54 Fla. L. Rev. at 757. The cost savings of settlement, both to the parties and to the public, are equally widely-recognized. *See Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) ("Public policy favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming.").

sufficiently apparent that antitrust liability would not undermine the encouragement of genuine invention and disclosure. *Cf. Walker Process*, 382 U.S. at 179-180, 86 S. Ct. at 351 (Harlan, J., concurring) (noting that exposing patentees to antitrust liability for the assertion of a patent known to have been procured by fraud "cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure"). In this regard we note that some lower courts have extended *Walker Process* to permit antitrust claims against patentees for the anticompetitive effects of infringement lawsuits when the antitrust claimant proves that the patentee knew that the patent was invalid, *Handgards*, 601 F.2d at 994-96, or knew that the patent was not infringed, *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 876-77 (Fed. Cir. 1985), *overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998).[21] To the extent that the appellees have demonstrated nothing more than subsequent invalidity, we hold that this alone is insufficient to render the patent's potential exclusionary effects irrelevant to the antitrust analysis.

C.

The class action plaintiffs-appellees argue that the patent right does not include the right to pay infringers, with the implication that any exclusion resulting from payment rather than judicial enforcement is not pro-

---

[21] Similarly, it has been suggested that the "sham" exception to the antitrust immunity afforded by the *Noerr-Pennington* doctrine is or may be available also to antitrust plaintiffs seeking to pierce the patent immunity. *See Independent Services Organizations*, 203 F.3d at 1326-27. Because the parties have not briefed such potential exceptions to the patent immunity from antitrust liability, we do not address them at this time.

tected from per se antitrust liability by the patent laws. Our discussion with regard to the important role played by settlement in the enforcement of patent rights leads us to reject this argument as well. Appellees have not explained why a monetary payment as part of a patent litigation settlement should be flatly prohibited as a *per se* violation, particularly where the alleged infringer has not yet caused the patentee any harm and the patentee does not have a damages claim to bargain with. *See Ciprofloxacin*, 261 F. Supp. 2d at 251-52 (discussing the asymmetries of litigation risk created by Hatch-Waxman and rejecting the argument that payments from the patentee to the infringer are subject to *per se* antitrust analysis); Crane, 54 Fla. L. Rev. at 774 (discussing the dynamics of settlement before the alleged infringer has entered the market).

We cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements. If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement. *See Aro Corp.*, 531 F.2d at 1372. To hold that an ostensibly reasonable settlement of patent litigation gives rise to *per se* antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a *per se* rule

would be an appropriate accommodation of the competing policies of the patent and antitrust laws.

It may be that the size of the payment to refrain from competing, sometimes called a "reverse payment" or an "exit payment," raises the suspicion that the parties lacked faith in the validity of the patent[22], particularly when those payments are non-refundable in the event that the patentee prevails on the infringement claim (as a bond posted as part of a preliminary injunction would be). However, in the instant case and given the state of the current record, it is difficult to infer from the size of the payments alone that the infringement suits lacked merit. We do not know, for example, what lost profits Abbott expected from generic competition or what profits Geneva and Zenith expected to gain from entry, the risk of the defendants' inability to satisfy a judgment, or the litigation costs each side expected to save from settlement. We do not know how much of the payment might have been in exchange for provisions of the Agreements other than Zenith's and Geneva's acknowledgment of validity.[23] Without these facts we cannot confidently draw the conclusion, merely from the size of the payments, that there were no genuine disputes over the validity of the patent. Given the asymmetries of risk and large profits at stake, even a patentee confident in

---

[22] For example, the size of the payments might be evidence supporting a claim that the patentee knew that the patent was procured by fraud, or knew that the patent was invalid, or that there was no objective basis to believe the patent was valid. *See* discussion in Part B, *supra*.

[23] For example, it seems reasonable to assume that part of the payments to Geneva were in return for Geneva's agreement not to waive its 180-day exclusivity period. Payments for provisions other than the acknowledgment of validity would not shed light on the parties' evaluations of the merits of the validity issue.

the validity of its patent might pay a potential infringer a substantial sum in settlement. *See, e.g., Ciprofloxacin Hydrochloride*, 261 F. Supp. 2d at 196, 234 (settlement agreements under which a patentee paid an infringer $49.1 million to acknowledge the validity of a patent, and at least $398 million for the infringer to remain off the market, though the patent was subsequently approved by the PTO on reexamination and unsuccessfully challenged in court three times).

Another possibly suspicious characteristic of the payments to Geneva is their structure (i.e., tying their duration to the length of the litigation), which, as the district court noted, may have given Geneva an incentive to delay resolution of the infringement suit.[24] But if the payments were in furtherance of the seemingly reasonable purpose of compensating Geneva for any lost profits during the course of litigation (much like a bond posted as part of a preliminary injunction), it is difficult to imagine how else to structure the payments but by tying them to the length of the litigation.

We recognize that the Sixth Circuit appeared to take the opposite view in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) ("[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competition by paying the only potential competitor $40 million per year to stay out of the market.").[25] When the exclusionary power of a patent is implicated, however, the antitrust analysis

---

[24] Neither appellees nor the district court have offered any similar suspicions with regard to the structure of payments under the Zenith Agreement.

[25] The terms of the agreements at issue in the *Cardizem CD* case were similar to the terms of the Agreements in this case.

cannot ignore the scope of the patent exclusion. "[T]he protection of the patent laws and the coverage of the antitrust laws are not separate issues." *Studiengesellschaft*, 670 F.2d at 1128. As the above discussion indicates, we do not think that a payment from the patentee to the alleged infringer should be automatically condemned under the antitrust laws[26], nor do we think that the evidence regarding the exit payments in this case allows a confident conclusion to be drawn at this stage of the litigation that the exclusionary effect of the Agreements were bolstered by the exit payments to a degree that exceeds the potential exclusionary power of the patent.

Because these matters were given scant attention in the district court, considering the court's primary con-

---

[26] The Sixth Circuit seems to have placed considerable reliance upon the generic's agreement to delay entering the market in exchange for exit payments, although it may also have been influenced by other provisions of the agreement which might more readily seem to exceed the potential exclusionary power of the patent. For example, the Sixth Circuit mentioned the effect of the agreements regarding the 180-day exclusivity period as well, and its reference to the district court opinion in that case might reflect some reliance on the restriction on non-infringing products. *See Cardizem CD*, 332 F.3d at 907-08; *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 705 (E.D.Mich. 2000). However, the Sixth Circuit opinion did not purport to measure the several provisions against the exclusionary power of the patent, or differentiate between provisions that fell within the scope of the patent's protection and those which did not. *Cf. Cardizem CD*, 105 F. Supp. 2d at 701 ("The anticompetitive effects of [the] patent are likewise not at issue."). To the extent that the Sixth Circuit suggests that a settlement of patent litigation was a *per se* violation of the antitrust laws merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, we respectfully disagree. We believe that the potential exclusionary power of the patent must first be considered.

clusion that the Agreements were market division agreements like those in *Palmer* and Topco, these questions have not been explored. We simply note them here to explain our conclusion that the presence of an exit payment as part of the settlement does not alone demonstrate that the Agreements had obvious anticompetitive tendencies above and beyond Abbott's potential exclusionary rights under the '207 patent.

D.

Our discussion so far has been limited to the exclusionary effects of the instant Agreements to delay entrance into the market, the subsequent invalidation of the patent, and the mere fact of exit payments. To the extent that these or other effects of the Agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to *per se* antitrust condemnation.[27] From the preceding discussion, we conclude that deciding the antitrust implications of these exclusionary effects requires an analysis of the effects of antitrust liability on the innovation and disclosure incentives created by the patent regime, with the aim of "achieving a suitable accommodation between the differing policies." *Walker Process*, 382 U.S. at 179, 86 S. Ct. at 351 (Harlan, J., concurring).

As alluded to earlier, however, *see supra* at ___ n.18 (M/S at 26, n.18), the instant Agreements are not con-

---

[27] Application of rule of reason analysis is similarly inappropriate, as the anticompetitive effects of exclusion cannot be seriously debated. Rule of reason and *per se* analysis are both aimed at assessing the anticompetitive effects of particular conduct; what is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects.

fined to matters involving restrictions on infringing products, exit payments, and a subsequent court decision declaring the patent invalid. Appellees also challenge other provisions of the Agreements, such as those prohibiting the marketing of "any" generic terazosin product; Geneva's agreement not to waive its 180-day exclusivity period; and Geneva's agreement not to come to market until a final, unappealable judgment of invalidity rather than on a district court judgment. These arguments require consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the Agreements exceed that scope, and the anticompetitive effects thereof. Because these considerations require a different analytic framework than that applied by the district court and advocated by the parties on appeal, it is appropriate to remand to the district court to apply an appropriate framework derived from this decision, and the arguments of the parties and the facts developed on remand. To aid in the development of an appropriate framework, we offer the following observations.

We recognize the patent exception to antitrust liability, but also recognize that the exception is limited by the terms of the patent and the statutory rights granted the patentee. "The precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise." *Line Material*, 333 U.S. at 300, 68 S. Ct. at 557. *See also New Wrinkle*, 342 U.S. at 378, 72 S. Ct. at 353 ("Patents give no protection from the prohibitions of the Sherman Act to [price fixing] when the licenses are used, as here, in the scheme to restrain."); *United States v. Masonite Corp.*, 316 U.S. 265, 277, 62 S. Ct. 1070, 1077 (1942) ("The owner of a patent cannot extend his statutory grant by contract or agreement. A

patent affords no immunity for a monopoly not fairly or plainly within the grant.").

The appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law[28] and consideration of the extent to which the Agreements reflect a reasonable implementation of these. Appellants, for example, contend that certain provisions of the Geneva Agreement are analogous to a consensual preliminary injunction and stay of judgment pending appeal. To evaluate this claim, the provisions of this Agreement should be compared to the protections afforded by the preliminary injunction and stay mechanisms and considered in light of the likelihood of Abbott's obtaining such protections. *Cf.* Hovenkamp at ¶ 2046 ("some care must be taken to ensure that . . . the settlement . . . is not more anticompetitive than a likely outcome of the litigation").

Any provisions of the Agreements found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act.[29] *Standard Oil Co., Ind., v. United States*, 283 U.S. 163, 175, 51 S. Ct. 421, 425-26, 75 L. Ed. 926 (1931) (recognizing that cross-licensing agree-

---

[28] We express no view at this time on what role the FDA's regulation of market entry might play in the appropriate antitrust analysis.

[29] Courts have not hesitated to apply traditional antitrust principles to agreements not within the scope of the patent protection. *See Line Material*, 333 U.S. at 307, 68 S. Ct. at 560 (holding a patent pooling agreement that fixed the prices at which licensees would sell the patented product *per se* illegal); *Masonite*, 316 U.S. at 274, 62 S. Ct. at 1076 (holding a price-fixing agreement among patentees and their licensees *per se* illegal).

ments and a division of royalties could be used to monopolize or fix prices and examining the evidence to assess the potential for anticompetitive effects as a result of the agreements at issue). The appropriate analysis of the market effects of such provisions may depend on the nature of the provision challenged. It may be that some challenged provisions are so obviously anticompetitive that they can be condemned as illegal on the evidence so far adduced, or it may be that the tendencies of some challenged provisions cannot be confidently predicted without further inquiry.

> [T]here is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment. What is required, rather, in an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint.

Cal. Dental, 526 U.S. at 780-81, 119 S. Ct. at 1618.[30] If on remand the court should conclude that part, but not all, of the provisions of the Agreements violate the Sherman Act, it may also be helpful to identify with specificity which provisions or combination of provisions are illegal[31] and the nature of the anticompetitive effects of

---

[30] Because the appellants' arguments supporting the application of the rule of reason rely primarily on the circumstance that the Agreements arise out of patent litigation, and because the determination of the appropriate analysis should await the inquiries to be made on remand, we decline at this time to address the issue further. We note, however, that the application of the rule of reason is not synonymous with exhaustive factual inquiry. "[S]ome rule-of-reason cases can be disposed of merely on the basis of the parties' arguments and, more often, on the basis of a limited summary judgment record." Hovenkamp, ¶ 1508.

[31] This is not to suggest that the provisions should be considered in isolation; agreements that are anticompetitive when consid-

those provisions or combinations in order to aid subsequent determinations on causation and antitrust injury. Finally, the particular circumstances of this case and the arguments of the parties on remand may demonstrate other relevant considerations.

IV. CONCLUSION

The district court's order granting partial summary judgment is REVERSED and this case is REMANDED for further proceedings consistent with this opinion.[32]

---

ered in isolation (such as covenants not to compete) can still be lawful if they are ancillary to another agreement and, when viewed in combination, will have the overall effect of enhancing competition. *See Business Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 729, 99 L. Ed. 2d 808, 108 S. Ct. 1515, 1523 & n.3 (1988), *Polk Bros.*, 776 F.2d at 189. We simply suggest that careful consideration of individual provisions may be helpful should it appear that the Agreements are unlawful only in part.

[32] All pending motions are DENIED.